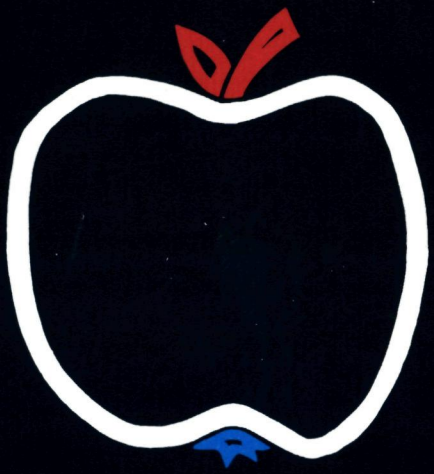
Implant-retained mandibular overdentures

clinical evaluation, satisfaction and mastication



Mariëlle Geertman

A two-center study, Universities of Groningen and Nijmegen
Part Nijmegen

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de Medische Wetenschappen

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aan mijn moeder

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CONTENTS

CHAPTER 1

GENERAL INTRODUCTION

The continuous resorption of the alveolar ridge after extraction of all teeth can eventually result in an unfavourable denture bearing area Consequently, denture support as well as retention and stability decrease As alveolar bone resorption tends to affect the mandible more than the maxilla many edentulous patients complain about an inadequate function of the mandibular denture

For many of these patients the construction of a set of dentures of high quality will solve their problems Sometimes additional minor surgical corrections are necessary to optimize the condition of the oral tissues However, when severe alveolar ridge resorption has taken place, more extensive preprosthetic surgical procedures like vestibuloplasty, deepening of the floor of the mouth and ridge augmentation may be indicated to improve and enlarge the denture-bearing area In literature there is common agreement that a total height of the mandible less than 15 mm poses technical problems for a vestibuloplasty and deepening of the floor of the mouth (Stoelinga, 1984) A treatment option for a mandibular bone height of less than 15 mm is ridge augmentation But this treatment has several disadvantages The gain in height of the alveolar ridge will diminish in the years after surgery and disturbances of the mental nerve often occur Stoelinga (1984) reported 48% loss of bone within five years after surgery, Freihofer and Hoppenreijs (1986) 50% Moreover the latter reported 29% of the mental nerves showed disturbances in function one year after augmentation Currently dental implants seem to become a more reliable form of treatment for these patients

Most studies concerning different aspects of dental implants in edentulous patients, like clinical success-rates, evaluation according to the patient's view and masticatory performance, describe the effects of mandibular implant-supported fixed prostheses Few studies have reported on implant-retained overdentures With respect to clinical success a high rate of success has been documented in long-term studies of implants supporting fixed prostheses in edentulous jaws (Adell *et al*, 1990, Albrektsson *et al*, 1988) However, reports about implants retaining mandibular overdentures have been presented in more recent years (Enquist *et al*, 1988, Gotfredsen *et al* 1993, Mericske-Stern & Zarb, 1993, Batenburg *et al*, 1994, Feine *et al*, Mericske-Stern *et al*, 1994, Naert *et al*, 1994) The results seem to be comparable with those of implants supporting fixed prostheses

Most studies do not exclusively report on patients with severely resorbed alveolar ridges (Class VI, Cawood, 1988) A maximum height of the alveolar ridge as an inclusion criterion is almost never mentioned, only a minimum height requested for implantation is described Triplett *et al* (1991) studied 28 patients with severely resorbed mandibles treated with a an implant-supported fixed prosthesis or with an overdenture on Brånemark implants The overall survival-rate of individual implants was 94% one year after treatment Donatsky (1993) studied 25 patients with severe alveolar bone loss who were treated with Brånemark implants and ball attachments to stabilize an overdenture A success-rate of 97% one year after treatment was reported Both studies, however, are retrospective and mainly focused on clinical aspects

With respect to the evaluation according to the patients' views some studies have been published concerning implant-supported fixed mandibular prostheses Blomberg and Lindquist (1983) studied patients' reactions before and after placement of the prostheses the majority of them reported improvement of their quality of life, regained self-confidence and acceptance of the prosthesis as a part of themselves Hoogstraten and Lamers (1987) compared satisfaction of patients with fixed prostheses to satisfaction of patients with complete dentures Results showed that the patients with fixed prostheses were much more satisfied Kiyak *et al* (1990) conducted a longitudinal study to assess the psychological impact of dental implant treatment at different stages in treatment, satisfaction was high Concerning implant-retained mandibular overdentures few studies have been published Clancy *et al* (1991) and Wismeijer *et al* (1992) showed that the vast majority of the patients was satisfied with their overdenture Corresponding results were found by Van Waas and Bosker (1989) However, these studies did not compare different implant systems, nor implant treatment with a control treatment

Although patients with varying numbers of missing teeth may benefit from implants in terms of their masticatory performance (Haraldson and Carlsson, 1979, Lundqvist and Haraldson, 1992), conflicting results have been reported regarding the effects of such treatment in edentulous patients Lindquist and Carlsson (1985) found that the masticatory performance improved significantly after the insertion of four to six implants in the mandible and the provision of fixed mandibular prostheses Haraldson *et al* (1988), however, observed no significant change in masticatory performance after the provision of mandibu-

lar overdentures retained by two implants The results of these two studies suggest that the improvement in masticatory performance depends upon the degree of support of mandibular prostheses by implants However, a comparison of these studies can be made only with caution Both studies were restricted to measuring the effects of a single treatment procedure and the studies may have differed in the selection of patients eligible for treatment

Few studies have been published in which different implant systems retaining overdentures were compared Due to the lack of identical evaluation criteria and differences in selection criteria and patients' characteristics it is impossible to make a comparison of studies in which only one implant system is used The only study design that enables comparison of different implant systems is a phase III randomized clinical trial In spite of recommendations to perform clinical trials (Kapur and Garrett, 1988, Quayle 1988, Meinert, 1990, Fiorellini & Weber, 1994) this study design is seldom applied in implant dentistry Kapur (1987) compared in a randomized clinical trial the effectiveness of fixed partial prostheses retained by a blade-vent implant with removable partial dentures in partially edentulous patients (Kennedy Class I) Only de Grandmont *et al* (1994) and Feine *et al* (1994) reported about treatment of edentulous patients in a clinical trial They made intra-individual comparisons between implant-supported fixed mandibular prostheses and long-bar implant-supported overdentures

No studies of edentulous patients have been published in which different implant systems were compared with each other and with conventional complete dentures serving as a control group For that reason a two-center randomized clinical trial was started The aim of this study was to compare the treatment effects of implant-retained mandibular overdentures, using three different implant systems, with new conventional complete dentures The outcome assessment includes a clinical evaluation as well as a subjective evaluation

STUDY DESIGN

This study is part of the Academic Dutch Implant Overdenture Study (ADIOS), a two-center clinical trial of patients with persistent problems wearing conventional complete dentures They were referred by general practitioners to a University clinic Two clinics participated in this study, e g the Departments of

Oral Function and Prosthetic Dentistry and of Oral and Maxillofacial Surgery (University of Nijmegen) and the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics (University Hospital Groningen)
The sample size was aimed at 240 subjects

- 120 Subjects were to receive an **I**mplant-**R**etained mandibular **O**verdenture (**IRO**), and a new conventional maxillary denture
- 30 Subjects were to receive a conventional mandibular denture after PreProsthethic Surgery (PPS), and a conventional maxillary denture
- 90 Subjects were to receive a **C**onventional mandibular and maxillary **D**entures (**CD**)

Three different implant systems were applied

- The Brånemark system (Nobelpharma, AB, Goteborg, Sweden), a titanium screw-type cylinder (**BRÅ**)
- The IMZ system (Friedrichsfeld, Mannheim, Germany), a titanium cylinder with titanium-plasma-spray coating (**IMZ**)
- The transmandibular implant system according to Bosker (Krijnen, Medical BV, Beesd, the Netherlands), consisting of a baseplate, four posts and five cortical screws made of a gold-alloy (**TMI**)

The preprosthetic surgery was carried out according to the buccal onlay procedure (Hopkins, 1987, PPS) in combination with a deepening of the floor of the mouth according to the Brown-Downton-Caldwell procedure (Stoelinga, 1984)

This clinical trial consisted of three different parts (table 1 1)
- Nijmegen In Nijmegen patients with a mandibular symphyseal bone height between 8 and 15 mm, as measured on a standardized lateral cephalogram, were selected The intended number of patients was 90 30 patients with two IMZ-implants and an implant-tissue supported overdenture with a single bar-clip attachment, 30 with a TMI and a mainly implant-supported overdenture with five clips on a triple-bar construction, and 30 with a conventional mandibular denture
- Groningen I Patients with a mandibular symphyseal bone height between 8 and 15mm were selected The intended number of patients was 60 30 patients with two IMZ- or two Brånemark implants with an implant-tissue supported over-

denture with a single bar-clip attachment and 30 with a conventional mandibular denture

- Groningen II Patients with a mandibular symphyseal bone height between 16 and 25 mm were selected The intended number of patients was 90 30 patients with two IMZ- or two Brånemark implants with an implant-tissue supported overdenture with a single bar-clip attachment, 30 patients with a conventional mandibular denture after preprosthetic surgery and 30 with a conventional mandibular denture

The design of the study differed in one aspect between the two centers the ethical committee at the University of Nijmegen gave approval for a randomized clinical trial, at the University of Groningen the ethical committee required pre-randomization (randomized consent trial, Pocock, 1983, Zelen, 1990, Chapter 2)

Table 1.1 Intended number of patients

Nijmegen (8-15 mm)	**n=90**
IMZ implants + overdenture	30
TMI system + overdenture	30
Conventional denture	30
Groningen I (8-15 mm)	**n=60**
Permucosal implants* + overdenture	30
Conventional denture	30
Groningen II (16-25 mm)	**n=90**
Permucosal implants* + overdenture	
Preprosthetic surgery +	30
conventional denture	30
Conventional denture	30

* Branemark or IMZ implants

Treatment was allocated using a balancing procedure (Zielhuis *et al*, 1990), aiming at an equal distribution of patients over the treatment groups regarding variables that may interfere with the outcome of the study (balancing criteria) The balancing criteria were age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphyseal bone

height of the mandible. A computer-program was used for the allocation of the treatment to the patients.

Since some patients refused treatment after allocation the 'Intention To Treat' principle was applied (Pocock, 1983; Antczak-Bouckmos and Chalmers, 1988). This implies that patients are evaluated in the originally allocated treatment group regardless the actual treatment they received. The 'Intention to Treat' principle and the actual number of treated patients are described in Material and Methods of the Chapters 2, 4.2 and 5 of this thesis.

This clinical trial consists of three parts, which were carried out at two University clinics. Both clinics wanted to address specific questions. As a consequence the study is divided in a two-center part (patients with a mandibular symphyseal bone height between 8 and 15 mm: Nijmegen and Groningen I), and two separate parts in Nijmegen and Groningen. In Nijmegen special attention is paid to masticatory perfromance, in Groningen to psycho-social well-being, quality of life aspects and preprosthetic surgery. The specific objectives of the study in Groningen are described in the thesis of E.M. Boerrigter: Implant-retained mandibular overdentures; clinical and psychosocial aspects.

In this thesis the following questions will be addressed:

Two-center clinical trial

- To what extent does the treatment with dental implants and a mandibular overdenture contribute to the functioning of the complete denture?
- Are there any differences in satisfaction, complaints and chewing ability between implant-retained overdentures and complete dentures?
- Are there any differences between the three implant systems with respect to clinical aspects, i.e. peri-implant and radiographical parameters and surgical and prosthodontic complications?

Clinical trial Nijmegen

- Are there any differences in satisfaction, complaints, chewing ability and experiences with surgical procedures between implant-retained mandibular overdentures on two IMZ implants and on the TMI system?
- Are there any differences in masticatory performance between implant-retained overdentures and complete dentures, and between implant-retained overdentures on two IMZ implants and on the TMI system?

Outline of this thesis

Chapter 2 - 4 deal with the two-center part of the study The study design is described in detail in Chapter 2, along with the results of subjective chewing ability Complaints about the dentures and degree of satisfaction are described in Chapter 3 a comparison is made between implant-retained overdentures and complete dentures Chapter 4 deals with the clinical aspects of the two-center study In the first part of the chapter a clinical implant performance scale, developed according to the Delphi-method, is described A comparison of peri-implant parameters, radiographical evaluation and clinical implant performance is made for the three implant systems in the second part of this chapter

Chapter 5 - 7 deal with the specific aspects of the clinical trial in Nijmegen In Chapter 5 a comparison is made between an implant-tissue supported overdenture on two IMZ implants and a mainly implant-supported overdenture on a TMI with respect to experiences with surgical procedures, complaints, satisfaction and subjective chewing ability Differences between the three treatment modalities in comminution of food, using an artificial testfood, is described in chapter 6 In chapter 7 the relationship between the masticatory performance and chewing experience is presented

A general discussion of the findings is presented in chapter 8

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A TWO-CENTER CLINICAL TRIAL OF IMPLANT-RETAINED MANDIBULAR OVERDENTURES VERSUS COMPLETE DENTURES CHEWING ABILITY

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ABSTRACT

This study is a two-center clinical trial with the aim to assess the treatment effects of implant-retained mandibular overdentures versus conventional complete dentures Treatment had been assigned according to a balanced allocation method The following criteria were used to enhance the comparability of the treatment groups age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphysial bone height A total of 151 patients with severely resorbed mandibles participated in the study, they were treated at two centers Ninety-one patients received an implant retained mandibular overdenture (IRO) and 60 patients a conventional complete denture (CD) Since some patients refused the allocated treatment the 'Intention To Treat' principle was applied This implies that patients are evaluated in the originally allocated treatment group regardless the actual treatment they received Patient's experiences were evaluated before treatment and one year after insertion of the new dentures Results before treatment showed that both treatment groups were comparable they were dissatisfied with their mandibular denture and they could hardly chew tough or hard foods One year after insertion of the new dentures the IRO-group was satisfied with their mandibular denture, whereas only one third of the CD-group was satisfied With respect to the chewing ability the IRO group scored significantly better than the CD-group ($p \leq 0.0001$)

INTRODUCTION

The continuous resorption of the alveolar ridge after extraction of all teeth can eventually result in a jaw anatomy which offers inadequate support for dentures (Tallgren, 1972) Especially when the lower alveolar ridge has become severely reduced patients often complain about instability, pain and inability to chew tough or hard foods To improve denture retention and stability preprosthetic surgical techniques such as ridge augmentation, vestibuloplasty and lowering of the floor of the mouth were used up to five years ago with varying rates of success Currently osseointegrated implants seem to become a more reliable form of treatment for these patients

A high rate of success has been documented in long-term studies for osseointegrated implants supporting fixed prostheses in edentulous jaws (Albrektsson *et al*, 1987; Adell *et al*, 1990). Little attention, however, is paid to implant-retained overdentures. Reports have been published only in recent years. Short-term results (Johns *et al*, 1992; Gotfredsen *et al*, 1993; Naert *et al*, 1994) as well as results of five year longitudinal studies (Babbush and Shimura, 1993; Mericske-Stern *et al*, 1994) seem to be comparable with those of implants supporting fixed prostheses.

Few studies have reported on patients with severely resorbed mandibles (Class VI, Cawood and Howell, 1988). Triplett *et al* (1991) selected 28 subjects with a mandibular bone height of 10 mm or less who had been wearing an implant-retained prosthesis for at least one year. Nineteen patients had a fixed prosthesis and 9 an overdenture on Brånemark implants. The overall survival-rate (of individual implants) was 94% one year after treatment. Donatsky (1993) studied 26 patients with severe alveolar bone loss who were eligible for vestibuloplasty and lowering of the floor of the mouth with skin graft. They were treated with Brånemark implants and ball-attachments to stabilize an over-denture. A success-rate of 97% one year after treatment was reported. Both studies, however, are retrospective and mainly focused on clinical aspects.

Although considerable advancements have been made with osseointegrated implants during the last decades randomized controlled clinical trials have been lacking. In spite of recommendations to perform phase-III randomized clinical trials (Kapur and Garrett, 1988; Quayle, 1988; Meinert, 1990; Fiorellini and Weber, 1994)), most studies are not comparative since only one implant-system was used without a control-treatment. Kapur (1987) published about treatment with implants in a randomized clinical trial. In partially edentulous patients he compared the effectiveness of fixed partial prostheses retained by a blade-vent implant with removable partial prostheses dentures (Kennedy Class I). Only Feine *et al* (1994) and de Grandmont *et al* (1994) reported about treatment with implants in a clinical trial with edentulous patients. They compared different types of implant-retained prostheses: fixed and removable prostheses. No studies of edentulous patients with severely resorbed mandibles have been published in which different implant systems were compared. For that reason a two-center randomized clinical trial was started. The aim of the study was to compare the treatment effects of implant-retained

mandibular overdentures, using different implant-systems, with new conventional complete dentures Clinical as well as patient related aspects were evaluated In this paper the design of the study is presented Special attention is paid to patient selection, randomization and treatment refusal The results will focus on the subjective chewing ability

MATERIAL AND METHODS

Patient selection

The subjects selected for this study were edentulous patients with severely resorbed mandibles and persistent problems wearing conventional complete dentures They were referred by general practitioners to a University clinic Two clinics participated in this study, e g the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics (University Hospital Groningen) and the Department of Oral Function and Prosthetic Dentistry and the Department of Oral and Maxillofacial Surgery (University of Nijmegen) The subjects were screened for their eligibility by a prosthodontist and an oral surgeon To select patients with severely resorbed mandibles the mandibular symphysial bone height was measured on a standardized lateral cephalogram Patients with a bone height of 15 mm or less were eligible The criteria for inclusion in the clinical trial are summarized in table 2 1

Table 2.1 Inclusion-criteria

1	No history of preprosthetic surgery (e g vestibuloplasty)
2	A mandibular symphysial bone height of less than 15 mm, but more than 8 mm as measured on a standardized lateral cephalogram
3	No implants inserted before, neither in the mandible nor in the maxilla
4	The absence of medical risks interfering with the treatment or with (expected) implant success

Study design and sample size

The design of the study differed in one aspect between the two centers the ethical committee at the University of Nijmegen gave approval for a randomized clinical trial, i e eligible patients were asked to give their written consent for participation in the trial before allocation of treatment took place, at the University of Groningen the ethical committee required pre-randomization (randomized consent trial, Pocock, 1983, Zelen, 1990), i e treatment was allocated before patients gave their written consent Since some patients refused treatment after allocation the 'Intention To Treat' principle was applied (Pocock, 1983, Antczak-Bouckoms, 1988) This implies that patients are evaluated in the originally allocated treatment group regardless the actual treatment they received

The sample size was aimed at 150 subjects 90 subjects were to receive an **I**mplant-**R**etained mandibular **O**verdenture **(IRO)** and 60 subjects a **C**onventional mandibular **D**enture **(CD)** Three different implant systems were applied (a) the Brånemark-system (Nobelpharma, AB, Goteborg, Sweden), a titanium screw-type cylinder, (b) the IMZ-system (Friedrichsfeld, Mannheim, Germany), a titanium cylinder with titanium-plasma-spray coating, and (c) the transmandibular implant-system according to Bosker (Krijnen, Medical BV, Beesd, the Netherlands), consisting of a baseplate, four posts and five cortical screws made of a gold-alloy A conventional mandibular denture served as control treatment All patients received a new maxillary denture To be able to study the surplus value of implant-retained overdentures compared to conventional complete dentures all groups with implant-retained overdentures were taken together

Treatment assignment

Treatment was allocated using a balancing procedure (Zielhuis *et al*, 1990), aiming at an equal distribution of patients over the treatment groups regarding variables that may interfere with the outcome of the study (balancing criteria) In this trial the criteria were age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphysial bone height of the mandible A computer-program was used for the allocation of patients to the treatment groups

Surgical and prosthodontic procedures

In case of permucosal implants according to the Brånemark- (Brånemark *et al*, 1985) and IMZ-system (Kirsch and Mentag, 1986) two fixtures were interforaminally inserted under local anaesthesia Patients were not allowed to wear the mandibular denture during the first two weeks after surgery After initial woundhealing the denture was adjusted with a soft-liner and a soft diet was prescribed After a healing period of three months the second stage surgery was performed (i e abutment connection) The mandibular overdentures were supported by a single bar-clip attachment (fig 2 1 and 2 2) The transmandibular implant according to Bosker (Bosker, 1986) was inserted under general anaesthesia The day after surgery the superstructure was placed, consisting of a triple-bar construction with cantilever extensions (fig 2 3)

During a period of three months patients were not allowed to eat solid food nor to wear the mandibular denture After this period the manufacturing of the new maxillary denture and the mandibular overdenture was started

In all treatment groups the dentures were manufactured with an optimal fit and according to the balanced occlusion principle

Patient's experiences

Before treatment and one year after insertion of the new dentures patients were asked whether they were satisfied with their dentures in general, their mandibular and maxillary denture separately, and their chewing ability in general They were also asked to rate their opinion about their chewing ability of eight different types of food The items were measured on a 3 point ordinal scale Factor and reliability analyses were carried out on the questions about types of food On the initial scores three factors appeared 'soft food' (e g vegetables), 'tough food' (e g steak) and 'hard food' (apple, carrot)

The reliability coefficients Cronbachs' α appeared to be quite satisfactory for all factors, resp 0 74, 0 80 and 0 81 Final scores were calculated as the mean of the item score, ranging from 0 (good) up to 2 (bad) One year after treatment the scale structure was checked, changes in the originally constructed scales were not necessary Only the scale 'soft food' is left out in further analysis because it did not vary after treatment all patients were able to eat soft food

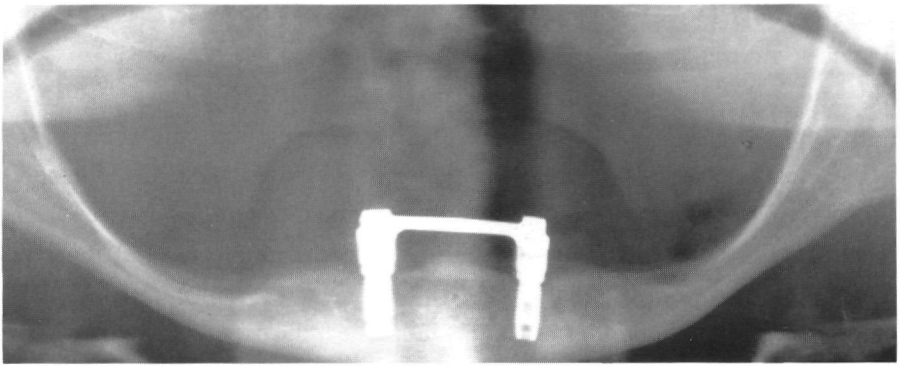

Figure 2.1 Two Brånemark implants with superstructure

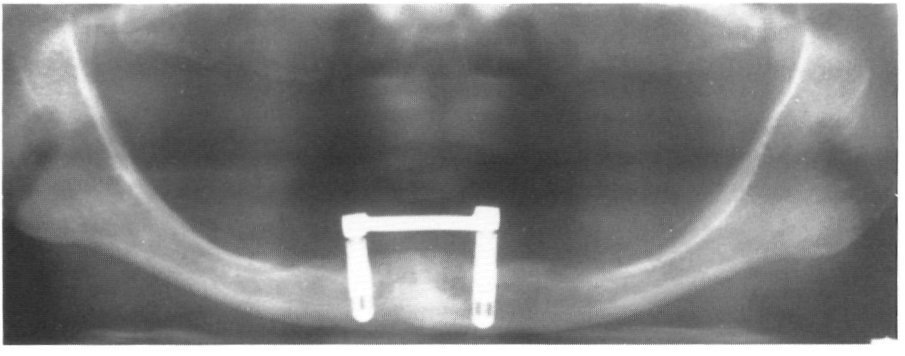

Figure 2.2 Two IMZ implants with superstructure

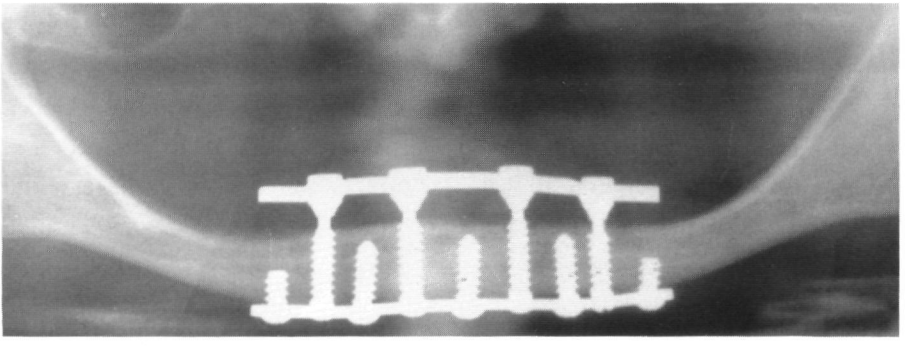

Figure 2.3 The transmandibular implant

Statistical analysis

Differences in treatment were analyzed using a two-way analysis of variance (ANOVA), according to treatment and center to correct for possible confounding. The data obtained at the one year evaluation were used to analyze the differences between the IRO- and CD-group rather than comparing the data before with the data after treatment ('difference scores'). The 'difference scores' were not analyzed for several reasons. Firstly, the measurement-error is encountered twice in the 'difference scores', while in the data of the one year evaluation the measurement-error is encountered only once. Secondly, the initial situation of the patients with respect to the quality of the complete dentures may have shown considerable differences. In the third place 'difference scores' may be subjected to a 'Regression to the Mean' effect (Fletcher *et al*, 1982) since the participants may be regarded as an extreme group of patients, given their ask for treatment (self selection).

RESULTS

Study sample

During the enrolment period from December 1989 till September 1991 treatment was allocated to 157 patients. Table 2.2 shows that 148 patients were treated according to allocation and 9 patients refused the allocated treatment. For the patients who refused the allocated treatment the 'Intention To Treat' principle was applied, as mentioned before. The distribution of the patients over the two treatment groups was as follows:

- At the baseline the IRO-group consisted of 93 patients: 88 of them received a implant-retained mandibular overdenture and a maxillary denture. The five patients who refused the allocated treatment did not want surgery and did not ask for any other treatment. One year after insertion of the new dentures two patients were lost to follow-up: they refused evaluation.
- The CD-group consisted of 64 patients at the baseline. Sixty of them received a set of conventional complete denture and 4 refused the allocated treatment. One patient wanted implants, one thought the treatment was too expensive and the other two did not expect any real improvement of new dentures. The patient who wanted implants received this treatment, but was

excluded from the study. The other three patients did not ask for further treatment. At the one year evaluation four patients were lost to follow-up: one died and three refused evaluation.

Table 2.2 Patients treated or not treated according to allocation

	Treatment according to allocation		**Treatment not according to allocation**		**Total**		
	baseline	1 year	baseline	1 year	baseline	dropout	1 year
IRO	88	86	5	5	**93**	2	**91**
CD	60	56	4	4	**64**	4	**60**
Total	148	142	9	9	**157**	6	**151***

* subjected to 'Intention to Treat' analysis

Since six patients did not participate in the one year evaluation 151 patients remained. This group consisted of 116 females and 35 males, their age varied from 35 to 84 years, with an average of 56 years (sd 9 yrs.). The characteristics of the patients and balancing criteria are presented in table 2.3. The comparability of all groups before treatment was tested by analysis of variance (2-way ANOVA) for the following variables: age, gender, edentulous period of the mandible and the maxilla, the number of mandibular and maxillary dentures, the age of the present mandibular and maxillary denture and the mandibular bone height. No significant differences were found except for the edentulous period in the mandible and the maxilla: the CD-group was edentulous for a significantly longer period than the IRO-group.

Table 2.3 Patient characteristics and balancing criteria {mean (SD) or percentages (%)}

		IRO n=91		CD n=60		TOTAL n=151	
Age in years[1] (SD)		55	(10)	58	(10)	56	(9)
Gender[1]	Male (%)	21		25		23	
	Female (%)	79		75		77	
Center	Groningen (%)	32		52		40	
	Nijmegen (%)	68		48		60	
Edentulous period mandible in yrs[1] (SD)		22	(8)	25	(9)	23	(9)
Edentulous period maxilla in yrs [1] (SD)		24	(9)	28	(9)	26	(9)
Number of mandibular dentures[1] (SD)		3	(1 5)	3	(1)	3	(1)
Number of maxillary dentures[1] (SD)		3	(1 5)	3	(1)	3	(1)
Age present mandibular denture[1] (SD)		6	(5)	7	(5)	7	(5)
Age present maxillary denture (SD)		7	(5)	7	(5)	7	(5)
Mandibular bone height in mm[1] (SD)		13 6	(1 5)	13 4	(2 0)	13 5	(1 7)

[1] Balancing criteria

Patient's experiences

Figure 2 4 shows the percentages of the answers to the questions about satisfaction with the dentures in general the mandibular and maxillary denture separately and chewing ability before treatment Patients in the IRO- and the CD-group were dissatisfied with the function of their dentures in general and especially the mandibular denture The mean scores before treatment of the chewing ability scale 'tough food' (range 0-2) were for the IRO-group 1 08 (sd 0 61) and the CD-group 0 97 (sd 0 56), for the scale 'hard food' (range 0-2) the scores were 1 75 (sd 0 49) and 1 85 (sd 0 30) respectively The results show that the majority of the patients had some or considerable problems chewing tough or hard foods Comparing the IRO-group with the CD group no significant differences were found for both scales (2-way ANOVA)

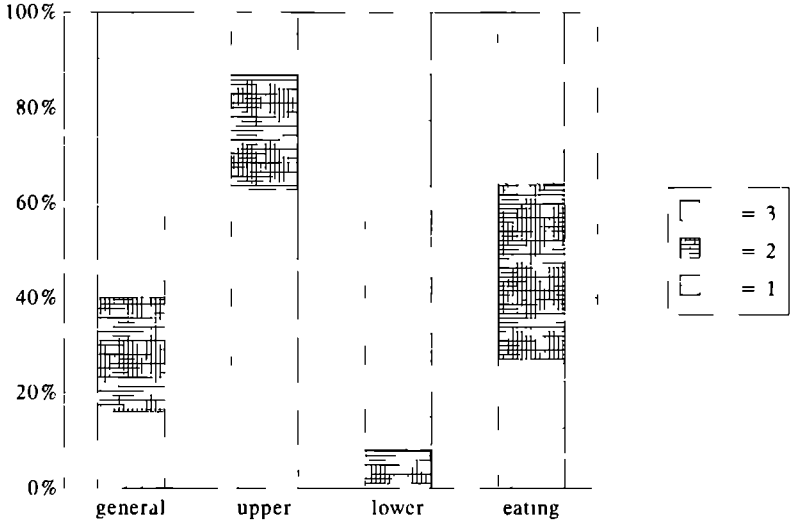

Figure 2.4 Distribution in percentages of answers to the questions about denture satisfaction before treatment

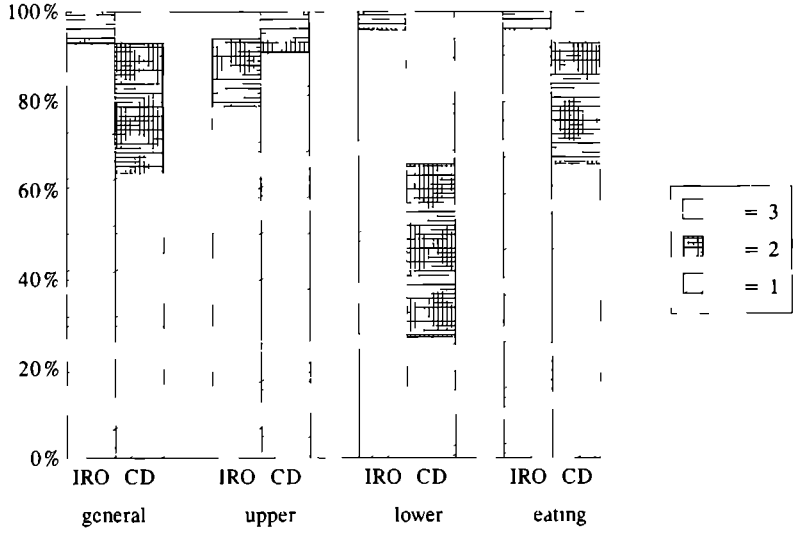

Figure 2.5 Distribution in percentages of answers to the questions about denture satisfaction one year after treatment

One year after insertion of the new dentures the IRO-group is satisfied in all aspects (fig. 2.5). Of the CD-group less than one third is satisfied with the mandibular denture, one third is dissatisfied and the others are neutral; with respect to the dentures in general 64% is satisfied.

Table 2.4 shows the results of the two chewing ability scales. The answers to the most representative question of each scale are presented in figure 2.6 and 2.7. At the question "Are you able to eat a steak ?" 83% of the IRO-group and only 32% of the CD-group answered positively. "Biting off a carrot" is still causing problems for 43% of the IRO-group and 63% of the CD-group. The mean scores on both scales showed significantly better scores ($p \leq 0.0001$) for the IRO-group compared to the CD-group (2-way ANOVA).

Table 2.4 Chewing ability one year after treatment

	IRO (n=91) mean (SD)	**CD (n=60) mean (SD)**	**Significance***
Tough food	0.19 (0.43)	0.72 (0.63)	$p \leq 0.0001$
Hard food	0.64 (0.67)	1.51 (0.61)	$p \leq 0.0001$

* 2-way ANOVA, range 0-2

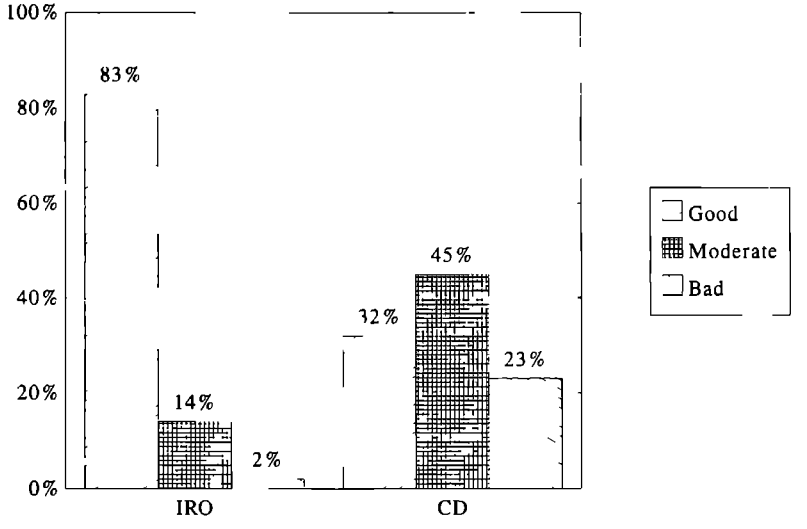

Figure 2.6 Percentages of the answers to the question 'Are you able to eat a steak ?'

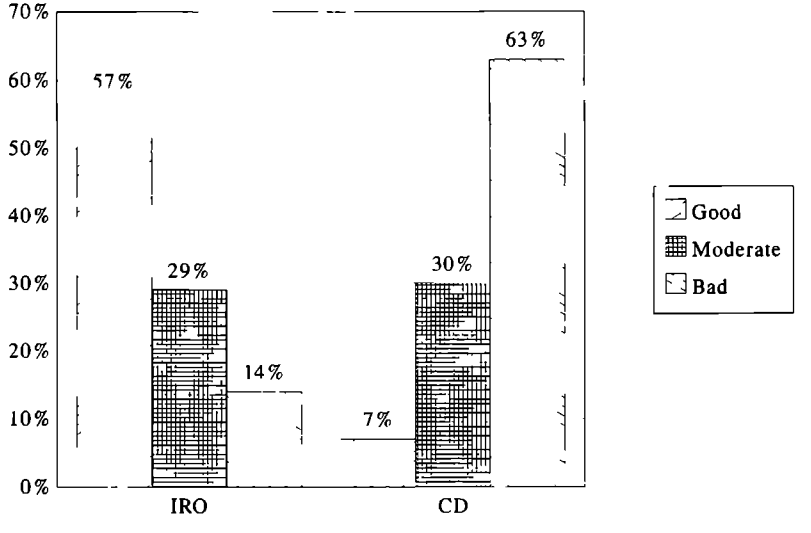

Figure 2.7 Percentages of the answers to the question 'Are you able to bite off a carrot ?'

DISCUSSION

In a clinical trial the experience of a group of patients on the new treatment is always evaluated by comparing it to a control group In this trial of implant-retained overdentures in patients with severely resorbed mandibles the standard treatment was chosen to be conventional complete dentures An option might have been ridge augmentation combined with vestibuloplasty and lowering of the floor of the mouth, followed by a set of new complete dentures But this treatment option has several disadvantages The gain in height of the alveolar ridge will diminish in the years after surgery and mental nerve disturbances occur Stoelinga (1984) reported 48% loss within five years after surgery, Freihofer and Hoppenreijs (1986) 50%, moreover 29% of the mental nerves showed disturbance in function one year after augmentation Taken into account these disadvantages, ridge augmentation was not considered to be a realistic control-treatment

The study was started in the fall of 1989 It took until september 1991 to select 157 patients who were eligible and willing to enter this clinical trial The long intake period can be partly explained by the inclusion-criteria (table 2 1) only patients with severely resorbed mandibles were allowed to enter the study Furthermore the balancing procedure was an uncertain factor for the patients There was a chance on implant treatment with general or local anaesthesia and on treatment with just a new set of dentures Therefore several patients refused consent

At entry into the trial the objectives and the consequences of participating in the trial were carefully explained to all patients to reduce treatment refusal Nevertheless, 9 of the 157 selected patients refused treatment after allocation had taken place To prevent selection bias the 'Intention To Treat' principle was applied (Pocock, 1983, Antczak-Bouckoms, 1988) This means that all patients are evaluated in the originally allocated treatment group regardless the actual treatment they received In consequence the contrast between the two treatment groups has probably diminished because patients who had refused implant treatment and had not received any treatment at all, were evaluated in the IRO-group, and vice versa patients who had refused complete dentures and received implant treatment were evaluated in the CD-group An alternative way to handle this problem was to evaluate only those patients who

had received the allocated treatment This would introduce selection bias with respect to motivation when comparing the IRO- with the CD-group The contemporary opinion in clinical epidemiology is to avoid selection bias and to choose for the 'Intention to Treat' principle (Lee *et al*, 1991)

The randomization method used for assignment of treatment to patients, resulted in two groups with comparable general characteristics at entry, only the mean edentulous period for both the maxilla and the mandible differed significantly between the two treatment-groups Patients' denture satisfaction before treatment was also comparable, as expected (fig 2 4) The same can be concluded for the chewing ability scales before treatment no significant differences between the IRO- and CD-group

One year after insertion of the new dentures the majority of the patients of the IRO-group were satisfied with their dentures and their chewing ability (fig 2 5-2 7)

Of the CD-group only one third was satisfied with the mandibular denture This was less than expected and not consistent with reports of Van Waas *et al* (1992) and Kalk *et al* (1992) In their study they compared three groups of patients one group treated with vestibuloplasty and lowering of the floor of the mouth, one group with severely resorbed mandibles and one group with normal ridges All groups had the same high degree of denture satisfaction

The answers of the CD-group to the question about denture satisfaction in general did not correspond with those of the mandibular denture about two third was satisfied with their dentures in general, while one third was satisfied with the mandibular denture This could be explained by the high rate of satisfaction with the maxillary denture

One year after insertion of the new dentures the IRO-group scored significantly better than the CD-group on the chewing ability scales These results are in accordance with those of Lindquist and Carlsson (1985) for fixed prostheses They found that the chewing ability improved significantly after insertion of mandibular fixed prostheses The results of Haraldson *et al* (1988) seem to be in contrast with the results of this study They reported no significant improvement in chewing ability after treatment with an implant- retained mandibular overdenture However, both these studies have several limitations the numbers of patients in these studies were small (27 resp 9), the selection of patients for treatment may have differed, treatment was not randomly assigned to

the patients and no control group was included The study of de Grandmont *et al* (1994) does not have these design flaws In a cross-over clinical trial patients assigned significantly higher scores to mandibular fixed prostheses as well as implant-retained mandibular overdentures with respect to chewing ability The results of our study are in correspondence with the results of de Grandmont *et al* (1994)

The mean scores of the chewing ability scales and the diagrams in Fig 2 6 and 2 7 show that the CD-group still had problems with chewing tough and hard food These results correspond with the study of Gunne and Wall (1985) They reported that new conventional complete dentures improved the subjective chewing ability, but chewing tough or hard foodstuffs was difficult

Comparing the results before and after treatment for the CD group the mean scores for the chewing ability scales have improved slightly Patients were also more positive about their complete dentures in general and mandibular and maxillary denture separately after treatment Conclusions, however, should be drawn with caution as a non-treated group was not included in this study and the improvement of the CD-group may also be due to a 'regression to the mean' effect (Fletcher *et al*, 1982) This could indicate some improvement for statistical reasons, without any real treatment benefit

Due to the two-center design of the study with a randomized treatment assignment this clinical trial provides a high external validity The results are valid for groups of denture wearers with persisting problems caused by severe resorption of the mandible, who are referred to a University Clinic After the first year results are positive for the implant group and negative for the complete denture group However, the long-term results remain to be evaluated in the future to assess the real benefits of this promising implant overdenture therapy

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PATIENT SATISFACTION WITH IMPLANT-RETAINED MANDIBULAR OVERDENTURES - A COMPARISON WITH NEW COMPLETE DENTURES NOT RETAINED BY IMPLANTS A MULTICENTER CLINICAL TRIAL

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ABSTRACT

Objective- The aim of this study is to establish the treatment outcome of full denture treatment with or without implant support, in which the outcome assessment focuses on the patient's subjective evaluation ('denture-satisfaction').
Design- A multicenter randomized clinical trial
Subjects- Thirty-four men and 117 women (mean age 56 ± 9, range 35 to 84 years) participated in the study. The mean height of the mandible was 13 ± 2 mm, measured on a lateral cephalometric radiograph. The patients were randomly assigned to either a group treated with implant-retained mandibular overdentures and a new maxillary denture, or to a control group treated with a new set of complete dentures.
Main outcome measures- Denture satisfaction was assessed using questionnaires focusing on denture-related complaints and 'a general satisfaction rate'.
Results- At the one year evaluation four of the six factors showed significantly better scores for the group treated with implants than for the control-group.
Conclusion- For patients with a severely resorbed mandible, overdentures retained by dental implants appear to provide a more satisfactory solution to their denture-related problems.

INTRODUCTION

Many edentulous people are dissatisfied with their set of dentures. It has been reported that approximately 15% of the dutch edentulous population has severe problems with the functioning of their complete dentures (Berg, 1991). Denture satisfaction is influenced by various factors, including denture quality, the denture bearing area available, the quality of dentist-patient interaction, previous denture experiences, and the patient's personality and psychologic well-being. After construction of a new set of dentures, the initial satisfaction tends to diminish over the years, which seems to be related to the changes of the denture bearing area as well as to the fading influence of the positive dentist-patient interaction (Vervoorn, 1988; Van Waas, 1990).

The continuous resorption of the alveolar bone gradually results in an impaired denture bearing area (Tallgren, 1972). As a consequence, denture support as well as retention and stability decrease. There is great interindividual

variation regarding the pattern of resorption, which is related to a combination of general and local factors The long term result is a complete loss of the bony alveolar ridge, causing an increased interarch distance, increased influence of surrounding soft tissue, decreased stability and retention of the prosthesis, and increased discomfort from improper prosthesis adaptation With time, the patient experiences increasing difficulty with functioning, which may eventually interfere with proper nutritional intake and with the ability to communicate with ease and confidence

Alveolar bone resorption tends to affect the mandible more than the maxilla This is probably related to a smaller bearing area and a less favourable distribution of occlusal forces (Tallgren, 1972) Consequently, the majority of edentulous people complain about an impaired function of the lower denture

For many patients, the construction of a new set of well-fitting dentures will initially resolve their problems Sometimes additional minor surgical corrections are beneficial to optimalize the condition of the oral tissues to improve support However, when severe bone resorption has taken place, preprosthetic surgical procedures in the form of buccal vestibuloplasty and deepening of the floor of the mouth may be indicated to improve and enlarge the denture-bearing area However in literature there is common agreement that a total height of the mandible less than 15 mm poses technical problems for such preprosthetic surgical procedures (Stoelinga, 1984)

Retention and stability problems can also be improved by the use of dental implants Long-term denture wearers with a deterioration in lower denture fit, may benefit greatly from an implant-retained overdenture (Albrektsson, 1987, Engquist, 1988, Naert, 1988, 1991) Until now, only a few predominantly retrospective studies have been carried out to evaluate the subjective effects of implant-retained overdentures Most studies focus on the technical aspects of the treatment outcome However, it is known that the outcome from the patient's point of view, in terms of denture satisfaction, is only in part related to technical aspects of the treatment modality (Vervoorn, 1988, Van Waas, 1990)

The present study is part of a multicenter randomized clinical trial addressing the treatment outcome of full denture treatment with or without implant support, in which the outcome assessment focuses on the patient's subjective evaluation

Denture satisfaction has been suggested to be the result of a combination of factors directly related to the treatment modality and factors not related to the technical part of the treatment (Vervoorn, 1988) Denture satisfaction can be assessed in general but can also be focused on aspects such as aesthetics, retention, and daily functioning The aim of this study was to compare the treatment results in two identical groups of patients having in common severe problems related to impaired functioning of mainly the lower denture The first group was treated with new dentures of which the lower denture was implant-retained The second and identical group was supplied with new complete dentures of a high quality (not retained by implants), as a control

MATERIALS AND METHODS

Patient selection

The present study was carried out at the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics of the University Hospital in Groningen, and at the Department of Oral Function and Prosthetic Dentistry of the University of Nijmegen The subjects were edentulous patients referred by their dentist or physician because of severe complaints about their lower denture To participate in the investigation the subjects were required have been edentulous in upper and lower jaw for at least one year In addition, a total mandibular jaw bone height of 8-15 mm (Cawood VI and VII, Cawood and Howell, 1988) as measured at the symphysis on a lateral cephalogram was an inclusion criterium Patients with either a history of pre-prosthetic surgery or previously treated with dental implants were excluded from the study Further exclusion criteria were general medical contra-indications for dental implants or a surgical procedure

Eligible subjects received a routine physical and radiographical examination The physical examination included an evaluation of the present set of dentures and the condition of the oral cavity The radiographical evaluation included further an orthopantomogram

All subjects were informed about the different treatment options, possible risks, and the method used for treatment assignment Informed written consent was required from all participating patients The ethical hospital committee in

Groningen required pre-randomization and the ethical hospital committee in Nijmegen gave approval for a randomized clinical trial (Pocock, 1983; Zelen, 1990).

Treatment assignment

Eligible patients were randomly assigned to either the group treated with an implant-retained overdenture in the lower jaw and a new denture in the upper jaw (**I**mplant-**R**etained **O**verdenture group, **IRO**), or a non-surgical treatment control group, who received a new set of dentures of high quality only (**C**onventional **D**entures group, **CD**). Assignment was executed by means of a balancing allocation method (Zielhuis, 1990) to ensure comparability of the groups regarding age, gender, edentulous period in the lower jaw, 'age' of the lower denture, and mandibular jaw bone height as measured on a lateral cephalogram.

Surgical and prosthodontic procedures

In case of permucosal implants according to Brånemark Implant system (Nobelpharma, AB, Göteborg, Sweden) or IMZ implants (Friedrichsfeld, Mannheim, Germany) two fixtures were inserted in the symphysial area under local anaesthesia. After a healing period of three months, the second phase (i.e. abutment connection) was performed. During this period a soft liner was applied in the lower denture. Three weeks after the second phase, a new maxillary denture and a mandibular overdenture on a round shaped Ackerman bar were manufactured. The transmandibular implant (TMI) according to Bosker (Krijnen Medical BV, Beesd, the Netherlands) was inserted under general anaesthesia. One day post-operatively the suprastructure was placed. After a healing period of three months, in which the patients did not wear their mandibular denture, the new maxillary denture and the mandibular overdenture were made.

The control group was treated by manufacturing a new set of dentures of high quality with an optimal fit and balanced occlusion and articulation.

Dependent variables

Treatment outcome from the patient's point of view was assessed using the following variables

- *Denture satisfaction*, assessed using a validated questionnaire, consisting of eight items focusing on the function of upper and lower dentures separately, and on specific features such as aesthetics, retention, and functional comfort Each item was presented with a five point rating scale on which the subject indicated to what extent he or she was (dis)satisfied with the respective denture (Vervoorn, 1988)
- *Complaints about the dentures,* assessed with a validated questionnaire consisting of 54 items (Vervoorn, 1988) The extent of each specific complaint could be expressed on a four point rating scale (0=no complaints, 1=little, 2=moderate, 3=severe complaints)
- The patient's *overall denture satisfaction* was expressed on a ten point rating scale (1-10)

Study design

Assessments were performed prior to treatment, and one year following insertion of the new set of dentures For subjects who refused the allocated treatment, the 'intention to treat' principle was applied (Pocock, 1983, Antczak-Bouckoms and Chalmers, 1988), implying that patients are evaluated in the originally allocated treatment group regardless of their actual treatment

Data analysis

The pre-treatment comparability of the groups was examined by analysis of variance (2-way ANOVA) of age, gender, edentulous period lower and upper jaw, number of lower and upper dentures, 'age' of the lower and upper denture, and the mandibular jaw bone height

Using the baseline data, principal component analysis with varimax rotation was used to explore the structure of the complaints questionnaire The reliability of the factors obtained was assessed by calculating Cronbach's coefficient α On each factor, final scores were calculated as the mean of the item score, ranging from 0 to 3

The one-year outcome for the two groups (IRO and CD) was analyzed by applying a two-way ANOVA. This was tested according to treatment and center, to correct for possible confounding.

In all statistical tests a significance level of 0.05 was chosen.

RESULTS

Study sample

A total of 157 patients obeying the inclusion criteria were referred in the period from December 1989 to September 1991.

After being assigned to the treatment groups, nine subjects refused the allocated treatment. Table 3.1 shows that 148 patients were treated according to allocation. For the patients who refused the allocated treatment the 'Intention To Treat' principle was applied.

Table 3.1 Patients treated or not treated according to allocation

	Treatment according to allocation		**Treatment not according to allocation**		**Total**		
	baseline	1 year	baseline	1 year	baseline	dropout	1 year
IRO	88	86	5	5	**93**	2	**91**
CD	60	56	4	4	**64**	4	**60**
Total	148	142	9	9	**157**	6	**151***

* subjected to 'Intention to Treat' analysis

At the one-year evaluation six patients dropped out due to death (one subject), and refusal for follow up (five subjects). All drop-outs were excluded from the study. Eighty-six patients were treated and evaluated with an overdenture on implants in the lower jaw and a new denture in the upper jaw. Fifty six patients were treated and evaluated with a new set of dentures only. The baseline data for the two groups is summarized in table 3.2. There were no significant differences between the two groups (CD and IRO) regarding age, gender, number of lower and upper dentures, age of the lower and upper denture, and mandibular jaw bone height (table 3.2), except for the edentulous period in the lower and upper jaw (2-way ANOVA).

Table 3.2 Characteristics of the study sample at the baseline

	IRO n=91	**CD n=60**	**TOTAL n=151**
Age in years (SD)	54.5 (9.7)	58.2 (10)	56.0 (9.4)
Gender Male (n)	19	15	34
Female (n)	72	45	117
Edentulous period mandible in yrs (SD)	21.7 (8.0)	25.4 (9.2)	23.2 (8.7)
Edentulous period maxilla in yrs[1] (SD)	24.3 (8.8)	27.8 (9.1)	25.7 (9.0)
Number of mandibular dentures (SD)	3.2 (1.5)	3.1 (1.2)	3.2 (1.4)
Number of maxillary dentures[1] (SD)	3.2 (1.5)	3.1 (1.2)	3.2 (1.3)
Mean age mandibular denture (SD)	6.4 (4.7)	6.9 (4.7)	6.6 (4.7)
Mean age maxillary denture[1] (SD)	6.7 (4.8)	7.1 (4.8)	6.9 (4.8)
Mean mandibular jaw height in mm (SD)	13.6 (1.5)	13.4 (2.0)	13.5 (1.7)

[1] The items concerning the upper jaw were not used at the balancing allocation method

Factor analysis of the questionnaires

Based on the baseline data, principal component factor analysis with varimax rotation of the 'denture complaints' questionnaire revealed six interpretable scales:

A. Complaints lower denture. This scale consisted of 12 items concerning functional problems of the lower denture, for instance 'Lower denture gets loose during eating' and 'Lower denture hurts eating hard food'.

B Complaints upper denture This scale consisted of seven items concerning functional problems of the upper denture, for example 'Upper denture gets loose during speaking' and 'Upper denture hurts eating granular food'

C Functional complaints in general This scale consisted of seven items concerning functional problems with the denture as a whole, for instance 'Teeth click while speaking' and 'Full sensation due to the denture'

D Physiognomy This scale consisted of three items concerning the aesthetics of the face, for instance 'Mouth has fallen in'

E 'Neutral space' This scale consisted of three items concerning accidental 'Lip biting', 'Cheek biting', and 'Tongue biting'

F 'Aesthetics' This scale consisted of three items concerning the aesthetics of the denture itself, for instance 'Teeth are too big'

Items with loadings higher than 0 40 on one factor and lower than 0 30 on the other factor were grouped into a scale (A-F) For all factors, the reliability appeared to be satisfactory, ranging from 0 76 to 0 90 (table 3 3) The outcome of the baseline data (prior to treatment) of the complaints questionnaire and the patient's overall denture satisfaction are summarized in table 3 4 There were no significant differences between the two groups (CD and IRO) prior to treatment

Table 3.3 Characteristics of the scales of the denture complaints and chewing ability questionnaire

	Number of items	**Cronbach's α**
Denture-complaints		
Functional complaints lower denture	12	0 90
Functional complaints upper denture	7	0 86
Functional complaints in general	7	0 76
Physiognomy	3	0 87
'Neutral space'	3	0 77
Aesthetics of the dentures	3	0 79

Table 3.4 Mean score (range 0-3) and SD of the denture complaints questionnaire and general satisfaction rate, prior to treatment

		IRO (n=91) mean (SD)	CD (n=60) mean (SD)	Significance[1]
Denture complaints				
A	Functional complaints mandibular denture	1.88 (0.68)	1.87 (0.73)	N.S.
B	Functional complaints maxillary denture	0.63 (0.62)	0.96 (0 71)	N.S.
C	Functional complaints in general	0.84 (0.65)	1.63 (0.90)	N.S.
D	Physiognomy	1.60 (1.01)	0.64 (0 73)	N.S.
E	'Neutral space'	0.42 (0 51)	0.64 (0.73)	N.S.
F	Aesthetics	0.58 (0.57)	0.57 (0.85)	N.S.
General satisfaction				
G	Satisfaction rate	4.42 (1.79)	4.48 (1.77)	N.S.

[1] 2-way ANOVA, N S = not significant, (SD) = standard deviation, range A-F is 0-3, range G is 1-10

Variable scores and treatment outcome comparison

In table 3.5, the outcome at the one-year follow-up is presented with regard to the denture complaints questionnaire and the general satisfaction rate. The factors 'functional complaints lower denture', 'functional complaints in general', and 'neutral space' showed significantly better scores for the IRO-group than for the CD-group. The scale 'Aesthetics' is left out in further analysis because it did not vary after treatment: all patients were satisfied with the aesthetics of their new dentures.

Table 3.5 Outcome of the denture complaints questionnaire and general satisfaction rate, one year after treatment

		IRO (n=91) mean (SD)	**CD (n=60)** mean (SD)	**Significance**[1]
Denture complaints				
A	Functional complaints mandibular denture	0.24 (0.38)	1.17 (0 74)	$p < 0.001$
B	Functional complaints maxillary denture	0.30 (0.39)	0.30 (0.34)	N.S.
C	Functional complaints in general	0.20 (0.28)	0.51 (0.55)	$p < 0.001$
D	Physiognomy	0.43 (0.64)	0 67 (0.86)	N.S.
E	'Neutral space'	0 15 (0.30)	0.36 (0.54)	$p < 0.003$
General satisfaction				
G	Satisfaction rate	8.37 (1.11)	6.58 (1.49)	$p < 0.001$

[1] 2-way ANOVA, N S = not significant; (SD) = standard deviation, range A-E is 0-3, range G is 1-10

Table 3.6 Distribution in percentages of answers on the denture satisfaction in general questionnaire, one year after treatment

		IRO (n=91)	CD (n=60)
How satisfied are you in general with your dentures?	1*	93	64
	2	7	29
	3	0	7
How satisfied are you with your upper dentures?	1	79	91
	2	15	9
	3	6	0
How satisfied are you with your lower dentures?	1	96	27
	2	4	39
	3	0	34
How satisfied are you with the appearance of your dentures?	1	95	87
	2	4	9
	3	1	4
How satisfied are you with the retention of your dentures?	1	84	32
	2	14	45
	3	2	23
How satisfied are you with the functional comfort of your dentures?	1	88	52
	2	12	30
	3	0	18
How satisfied are you about eating with your dentures?	1	96	66
	2	4	27
	3	0	7
How satisfied are you about speaking with your dentures?	1	95	63
	2	5	23
	3	0	14

* 1 = (very) satisfied, 2 = neutral, 3 = (very) dissatisfied

The same positive treatment effect mainly for the IRO-group is obvious for the general satisfaction rate. The distribution of the general satisfaction rate for the two groups is presented in figure 3.1 as an illustration. The scores for the IRO-group are explicitly shifted to the right which means significantly better scores for the IRO-group. Another illustration of this treatment effect could be observed with regard to the specific questions of the denture satisfaction questionnaire (table 3.6).

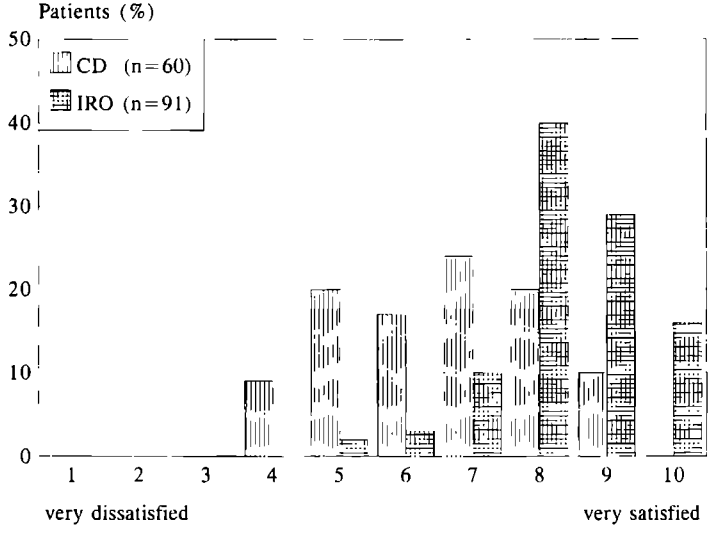

Figure 3.1 General satisfaction rate

DISCUSSION

Patients treated with an implant-retained overdenture in the lower jaw and a new denture in the upper jaw evaluated after one year appeared to be satisfied, especially with regard to their lower denture (table 3.5). This favourable outcome was also reflected by the overall satisfaction rate: the majority of the IRO-group (85%) had a score of 8 or even higher. These findings are consistent with those of previous studies (Van Waas and Bosker, 1989; Clancy *et al*, 1991;

Wismeijer *et al*, 1992, Harle and Anderson, 1993) The subjects under study were satisfied with implant treatment in general in terms of function, aesthetics, comfort and speech A proper basis for comparison is lacking due to the difference in indication for implant therapy, and the limits of the population surveyed In a study of Enquist *et al* (1988), 89 patients were treated with implant-retained overdentures The results were focused mainly on clinical aspects (i e failure rates in upper and lower jaw) The study sample was the result of a negative patient selection, because extreme bone resorption and poor bone quality were the reasons for indicating an implant-retained overdenture as an alternative to fixed implant supported bridges Naert *et al* (1988, 1991) reported two studies on overdentures and stated that the observation time was still too short to draw any definite conclusions, although the short time results were very promising
Mericske Stern (1990) and Zarb *et al* (1989) came to the same conclusion Controlled prospective studies have been carried out to evaluate the treatment by implant-retained overdentures (Haraldson *et al*, 1988, Engquist, 1991), however the number of patients included in their studies were small (9 respectively 28) Johns *et al* (1992) studied 133 patients, one year after insertion of an overdenture They concluded that the success rates of implant-retained overdentures in the mandible were comparable with those of fixed implant-supported bridges

The overall results of our study are in accordance with the favourable results achieved with jaw bone anchored bridges in the edentulous lower jaw (Blomberg and Lindquist, 1983, Hoogstraten and Lamers, 1987, Grogono *et al*, 1989, Kiyak *et al*, 1990, Kent and Johns, 1994) The studies by Blomberg *et al* (1983) and by Kiyak (1990), however, have an important drawback, i e the lack of a control group The inclusion of a control group is essential in assessing the real effects of a therapeutic procedure, especially when a new treatment option is evaluated Inclusion of a such a control group is particularly important when chronic problems are involved, because chronic denture problems tend to diminish over time (Kalk, 1979)

The results found in the CD-group, treated with a new set of conventional dentures of high quality, were less favourable than those in the IRO-group Regarding the main problem area in the CD-group, i e the lower denture, one third of the total number of patients was satisfied, but also one third was

dissatisfied. These results were more negative than in comparable research projects (Kalk *et al*, 1992; Van Waas *et al*, 1992). It was striking that 64% of the control group answered to be satisfied with the new dentures in general (table 3.6). However, when more specific information was considered, only 27% appeared to be satisfied with the new lower denture (table 3.6). The main reason for the satisfaction with the new dentures in general may be caused by the so called 'Care effect'. All the subjects in the control group were treated with a lot of patience and understanding for their problems. This may have resulted in a relatively high satisfaction with the treatment, at least at the one-year follow up period. As illustrated in table 3.6 the largest remaining problem in the CD-group is related to the retention of the dentures. Problems with functional comfort, eating and speaking are less important but still present (table 3.6).

The factor analysis of the complaint questionnaire produced six scales. The structure of these six scales were homogenous and largely in accordance with the original scales found by Vervoorn *et al* (1988). However, there are some slight differences. The original scale 'Functional complaints of the maxillary denture' consists of 12 items, our comparable scale consists of seven items. The main difference concerns some general items representing signs of an upper denture with decreased retention during eating or speaking. In contrast, our scale 'Functional complaints lower denture' consists of 12 items, while the originally scale of Vervoorn consists of eight items. This may be largely explained by the fact that our sample consists of subjects with severe resorption of the mandible (jawbone height of less than 15 mm). The majority of the subjects mainly searched for help because of problems with their lower denture. Thirty-five of the original 54 items could be placed into six interpretable scales, this is slightly different from the originally constructed scales by Vervoorn.

Compared to the CD-group, the IRO-group scored significantly better on the following factors of the denture complaints questionnaire: 'functional complaints lower denture', 'functional complaints in general', and 'neutral space'. The factor 'functional complaints upper denture' did not reveal significant differences between the two groups. This indicates that the patients derived the major benefit of the treatment from the improved function of the lower denture. It is sometimes assumed that patients treated with dental implants in the lower jaw afterwards may have more problems with their upper dentures (Naert, 1988). This supposition was not confirmed by our results (table 3.5).

The results of our study imply a considerable improvement of the lower denture's retention and stability as a result of implant support. However, a recent study also implies a major psychological benefit from dental implants (Kent and Johns, 1994). This may account, at least in part, for the higher overall satisfaction rate in the IRO-group.

The multicenter design of this study provides a high external validity of the results. Prevention of preferences in indications and treatments in one specific clinical setting is responsible for generalization at length of the results. The long term results (five and ten years), however, remain to be evaluated to assess the real benefits of this promising implant-overdenture treatment.

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CONSTRUCTION OF A CLINICAL IMPLANT PERFORMANCE SCALE FOR IMPLANT SYSTEMS WITH OVERDENTURES, USING THE DELPHI METHOD

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ABSTRACT

In order to compare the clinical performance of different implant systems retaining mandibular overdentures all kinds of problems and complications have to be considered, that can occur after implant placement, viz surgical, prosthetic, peri-implant and radiographic aspects Therefore, a five-point scale was constructed, named the clinical implant performance scale (CIP-scale) Each problem and complication that may occur after placement has to be scored The Delphi method was applied for this purpose It is a technique for obtaining answers to all kinds of questions that are issue of uncertainty, even to experts, giving a better guarantee for validity than the commonly used 'consensus between observers'

In the first Delphi-round six experts were asked to fill in a questionnaire in which a score should be given for each problem and complication that can occur after the osseointegration of the implants The scores were tabulated and the experts were asked to judge the items again, knowing the frequencies of the answers of the other experts After three rounds there was almost complete consensus present in 91% of the items for the permucosal implant systems and in 85% for the transmandibular system

Although some differences remained it can be concluded that, using the Delphi method, a reliable scale for evaluating the clinical performance of implant systems retaining mandibular overdentures is obtained

INTRODUCTION

Medical science is making progress in the implementation of quantitative methods to evaluate biological states and trends, using accurate and validated measurements of physiologic and biochemical processes There are, however, many clinical situations for which quantitative methods are not yet developed Such a clinical situation in dentistry is the clinical performance of implant systems retaining mandibular overdentures The use of such systems has increased during the last ten years (Schepers *et al* , 1991) Two to four implants are mostly inserted between the mental foramina and provided with a bar or ball attachments to give retention and stability for an overdenture Different implant systems are available some are called **permucosal systems**, consisting of two or

four cylindrical or screw-type implants, and others are called **transmandibular systems** and consist of a plate under the mandible with posts penetrating the mandible

To assess the clinical performance of different implant systems an inventory of the problems and complications that can occur after placement of the implants has to be made Subsequently a scale has to be constructed to assess all these problems and complications Each problem and complication that can occur after placement, has to receive a score on the scale which expresses the severity of the problem or complication with respect to the performance of the implant system Evaluating the clinical implant performance in this way enables a comparison of different implant systems Often, such scores are based on the judgements of one or two expert observers Judgements obtained in this way have been criticized because there is no way to assess their validity (Fink *et al*, 1984) The 'Delphi method', pioneered by Dalkey and his associates (1969), is a method that attempts to improve the quality and validity of such judgements (Milholland *et al*, 1973, Fink *et al*, 1984, Duffield, 1993, Williams and Webb, 1994)

The aim of this study was to construct a clinical implant performance scale (CIP-scale) for permucosal and transmandibular implant systems retaining mandibular overdentures, using the Delphi method

MATERIAL AND METHODS

Principles of the Delphi method

The Delphi method can be characterized as a technique structuring a group communication process so that the individuals of the group effectively deal with a complex problem To accomplish this 'structured communication', feedback of the individual contributions of information and knowledge, assessment of the group judgement or view, opportunity for individuals to revise views, and a degree of anonymity for the individual responses are necessary (Linstone and Turoff, 1975) These are the cardinal features in drawing out the group opinion anonymity, iteration, and feedback

Anonymity means that no member of the group knows what any other member answers to a particular question In this way verbal gifted experts can not impose their own view and the chance on socialization of the answers is

ruled out. It does not necessarily require that the identities of the other members are hidden; it may in fact be advantageous (motivating) if they are known. The questions are given in two or more **iterations**; in most of the cases these questions are the same in each round, but it is also possible that new questions are raised based on earlier responses. **Feedback**, closely allied to iteration, refers to the inclusion of additional information at each iteration in the form of statistics on the earlier responses of the group of experts as a whole.

The application is restricted in this article to problems and complications of different implant systems retaining mandibular overdentures in which the acquired answers are degrees of the clinical success of the systems. It is assumed that the true degrees of success associated with the problems and complications are in some sense present in the group of experts, and that by properly drawing out a group 'consensus', one obtains an well-considered degree of success for each problem and complication.

The most common form of the Delphi method is performed as follows: First a monitor team designs a scale with descriptions of the different categories and selects items for the questionnaire. This questionnaire is sent to a group, existing of invited experts who give their score for each item. The monitor team summarizes the results and develops, based upon the results, a new questionnaire for the experts. In the next rounds the experts re-evaluate their original scores based upon the examination of the responses of the other experts in the previous round. When experts strongly disagree they are asked for an explanation. The monitor team may directly react to the explanations and solve misunderstandings or may pass the explanation to the other experts. This procedure is repeated in the next round. The procedure ends when the opinions are to their nearest approach or when the divergence in the answers does not change any more.

Measuring clinical implant performance (CIP)

Three implant systems retaining mandibular overdentures in edentulous patients with severe mandibular bone loss were evaluated. Data were collected on base of case histories of 90 patients from a multicenter clinical trial, carried out at the Universities of Nijmegen and Groningen, concerning surgical, prosthetic, peri-implant and radiographic data (Geertman *et al*, 1994; Geertman *et al*, 1995; Boerrigter *et al*, 1995). The first two are the two-stage cylindrical IMZ-system and the screw-type Brånemark-system (Kirsch, 1983; Kirsch and Mentag, 1986;

Kirsch and Ackermann, 1989 Adell *et al*, 1981, Engquist, 1991) Two fixtures were inserted under local anaesthesia in the interforaminal part of the mandible They were connected with a bar, on which an overdenture with clip attachment was manufactured The third system, the transmandibular implant, developed and described by Bosker (Bosker, 1986, Bosker and Van Dijk, 1989, Powers *et al*, 1989), was placed by a submental approach under general anaesthesia It consists of a baseplate fixed to the caudal border of the mandible Four posts were screwed through the mandible and a superstructure was manufactured with a triple bar construction with cantilever extensions

For the construction of the CIP-scale all conceivable problems and complications that occurred during the first and second year evaluation Each aspect has to receive a score on the CIP-scale A five points scale, varying from category 0 (no problems) to category 4 (failure), was chosen (table 4 1 1)

Table 4.1.1 The categories in the clinical implant performance scale (the CIP-scale)

	Category
No problems	0
Minor problem that does not need intervention or is easily treated	1
Complication with reasonable chance of recovery or stabilisation of the situation	2
Serious complication that may lead to failure of the implant system	3
Failure of the implant system	4

For the peri-implant problems items were constructed based on a combination of an evaluation of the radiographs of the systems and the probing depths around the implants or implant posts The amount of bone loss, that was found when comparing the bone heights on the radiographs made directly after implantation with the bone heights on the radiographs made at a later time, was discriminated in four X-ray scores (0-3) Score 0 represents 'no bone loss', 1 represents 'bone loss less than 1/3 of the length of the implant or post', 2 'bone loss 1/3 to 1/2 of the length of the implant or post', and X-ray score 3 'bone loss more than 1/2 of the length of the implant of post' Probing depths were assessed at the buccal, lingual, mesial and distal sides of the implants or posts with a Merit B probe (Hu-Friedy), the highest values recorded were used Every

combination of 'bone loss' and 'probing depth' is presented as an item in the CIP-scale

Application of the Delphi method to the CIP-scale
In this study the Delphi procedure is performed in three phases

In phase one a list of problems and complications observed in the 90 above mentioned case histories of patients was made It was presented to a group of six experts, consisting of two oral surgeons and four prosthodontists Three of them are from the University of Nijmegen and three from the University of Groningen In a first round they were asked to assign each problem and complication to a category of the CIP scale They could also add items in this round

In phase two the assignments were tabulated in a list When there was consensus with respect to an item, the procedure ended, in case of different scores for an item the experts were asked to rate the item again in a second round If an expert disagreed with the score of the majority of the other experts he or she was asked for an explanation

In phase three the experts were consulted by telephone about the differences which still existed after the second round The procedure was ended when there were no differences or little divergence in judging the problems and complications

RESULTS

Table 4 1 2 and 4 1 3 show the lists of collected problems and complications in the permucosal and transmandibular implant systems separately and the odds of the given scores in every round of the Delphi procedure assigned to each item by the six experts After the first round one new problem was proposed by one expert with respect to the transmandibular systems the item 'loosening of one or more caudal screws of the posts' One expert did not assign scores to items 18 to 22 in the first round because of problems with the interpretation of these items In the second round a definition of these items was added to the questionnaire In the third round only items with differences in scores of 4 2 or 3 3 were presented again to experts by telephone This was necessary for four items of the permucosal implant systems and for eight items of the transmandibular implant system After three rounds there was complete agreement with respect to the

permucosal implant systems in 67% of the items, in 24% of the items there was one expert who had a different opinion, and in 9% of the items there were two experts with a different opinion With respect to the transmandibular implant system the experts completely agreed in 52% of the items, in 33% there was one expert with a different opinion and in 15% two experts had a different opinion Table 4 1 4 presents the final CIP scores for each problem and complication

Table 4.1.2 Items and diversity for the CIP-scale given by six experts in each Delphi round for the permucosal implant systems[1]

	Permucosal implant systems								
Problems and complications	odds first round			odds second round			odds third round		
01	Broken abutment	4	2		6	0			
02	Correction hyperplastic mucosa around implant	3	3		4	2		5	1
04	Correction not fitting superstructure	3	3		3	3		6	0
07	Broken superstructure	4	1		5	1			
08	Correction occlusion and articulation	6	0						
09	Loss of complete implant-system	6	0						
10	Loosening of one or more screws of the superstructure	6	0						
11	Relining upper or lower denture	6	0						
12	Minor disturbance mental nerve	4	2		4	2		4	2
13	Severe disturbance mental nerve	4	2		4	2		4	2
14	Replacement implant after fracture	3	2	1	6	0			
15	Removal of one implant	3	3		4	2		4	2
16	Removal of two implants	5	1		6	0			
18	X-ray score=0 and PD[b] 3 - 5 5 mm	5	0		6	0			
19	X ray score=0 and PD > 5 5 mm	5	0		6	0			
20	X ray score=1 and PD 0 - 3 mm	3	1	1	5	1			
21	X ray score=1 and PD 3 - 5 5 mm	4	1		5	1			
22	X-ray score=1 and PD > 5 5 mm	5	0		6	0			
23	X ray score=2 and PD 0 - 3 mm	6	0						
24	X-ray score=2 and PD 3 - 5 5 mm	6	0						
25	X ray score=2 and PD > 5 5 mm	4	2		6	0			
26	X-ray score=3 and PD 3 - 5 5 mm	5	1		6	0			
27	X ray score=3 and PD > 5 5 mm	4	2		5	1			

[a] the chosen categories are not presented in the table [b] PD = probing depth

Table 4.1.3 Items and diversity for the CIP-scale given by six experts in each Delphi round for the transmandibular implant system[a]

Transmandibular implant systems

Problems and complications	odds first round	odds second round	odds third round
02 Correction hyperplastic mucosa around implant	3 3	3 3	5 1
03 Correction one mobile post	4 2	4 2	4 2
04 Correction not fitting superstructure	3 3	4 2	6 0
05 Correction two mobile posts	4 2	3 3	5 1
06 Broken cantilever of superstructure	4 2	6 0	
07 Broken superstructure	4 1	6 0	
08 Correction occlusion and articulation	6 0		
09 Loss of complete implant system	6 0		
10 Loosening of one or more screws of the superstructure	6 0		
11 Relining upper or lower denture	6 0		
12 Minor disturbance mental nerve	4 2	4 2	4 2
13 Severe disturbance mental nerve	4 2	4 2	4 2
14 Replacement one or more posts after fracture	3 2 1	4 2	5 1
15 Removal of one post	5 1	5 1	
16 Removal of two posts	3 3	5 1	
17 Removal of three posts	5 1	6 0	
18 X ray score=0 and PD[b] 3 - 5 5 mm	5 0	6 0	
19 X ray score=0 and PD > 5 5 mm	5 0	6 0	
20 X-ray score=1 and PD 0 - 3 mm	3 1 1	6 0	
21 X-ray score=1 and PD 3 - 5 5 mm	4 1	5 1	
22 X ray score=1 and PD > 5 5 mm	5 1	6 0	
23 X ray score=2 and PD 0 3 mm	6 0		
24 X ray score=2 and PD 3 - 5 5 mm	6 0		
25 X ray score=2 and PD > 5 5 mm	4 2	5 1	
26 X ray score=3 and PD 3 - 5 5 mm	5 1	6 0	
27 X-ray score=3 and PD > 5 5 mm	4 2	5 1	
28 Loosening of one or more caudal screws of the posts	-	4 2	4 2

[a] see note table 4 1 2, [b] PD = probing depth

Table 4.1.4 The final CIP-scale based on the Delphi method

Problems and complications	transmandibular	permucosal
01 Broken abutment	*	1
02 Correction hyperplastic mucosa around implant	1	1
03 Correction one mobile post	3	*
04 Correction not fitting superstructure	2	2
05 Correction two mobile posts	3	*
06 Broken cantilever of the superstructure	1	*
07 Broken superstructure	2	2
08 Correction occlusion and articulation	1	1
09 Loss of complete implant-system	4	4
10 Loosening of one or more screws of the superstructure	2	1
11 Relining upper or lower denture	1	1
12 Minor disturbance mental nerve	1	1
13 Severe disturbance mental nerve	2	2
14 Replacement of one or more posts after fracture	2	4
15 Removal of one post/implant	3	4
16 Removal of two posts/implants	4	4
17 Removal of three posts	4	*
18 X-ray score=0 and probing depth 3-5.5 mm	0	0
19 X-ray score=0 and probing depth >5.5 mm	1	1
20 X-ray score=1 and probing depth 0-3 mm	1	1
21 X-ray score=1 and probing depth 3-5.5 mm	1	1
22 X-ray score=1 and probing depth >5.5 mm	2	2
23 X-ray score=2 and probing depth 0-3 mm	2	2
24 X-ray score=2 and probing depth 3-5.5 mm	2	2
25 X-ray score=2 and probing depth >5.5 mm	3	3
26 X-ray score=3 and probing depth 3-5.5 mm	3	3
27 X-ray score=3 and probing depth >5.5 mm	3	3
28 Loosening of one or more caudal screws of the posts	2	*

* not applicable for the corresponding implant system

DISCUSSION

The procedure went by uneventfully in general For some items there was a divergence in the scores between the oral surgeons and the prosthodontists The 'correction hyperplastic mucosa around implant', for instance, was a simple surgical problem in the view of the oral surgeons (category 1), but the prosthodontists had the opinion that a correction means a failure in managing of the patient's oral hygiene maintenance and that it is not a minor problem but a more serious complication (category 2) Disturbances of the mental nerve are a result of the surgery caused by the insertion of the implants or posts close to the mental nerve (Ellies, 1992) Some experts considered this as a complication of the implant (category 2), others as an unpleasant result of the surgery with no consequence for the success of the implant system (category 1) Discrimination between 'minor' and 'severe' did not improve consensus Concerning item 15, 'removing of one post of the transmandibular implant system' there is theoretically a failure of the implant, but the system and the overdenture are still in function, so category 3 was given

Tables 4 1 2 and 4 1 3 clearly show that there is a substantial increase in consensus from the first to the third round For many items there was not even a divergence in the views of the experts in the first round After the third round there was a high consistency regarding almost all items complete consensus or only one expert with a different opinion was present in 91% of the items for the permucosal implant systems and in 85% for the transmandibular system, i e there was a good convergence of the process

On base of high percentages of agreement it can be concluded that the CIP-scale gives a reasonable and satisfactory answer to the problem for assessing clinical implant performance in mandibular overdentures The scale is applicable for permucosal and transmandibular implant systems When the final patient score is obtained by taking the maximal score over all items, it makes comparison of different systems possible, not just on the basis of failures, as is mostly done in literature (Ten Bruggenkate *et al*, 1990) but on all problems and complications that can occur after implant insertion It differs from the implant success scale presented by Smith and Zarb (1989), since that scale evaluates implants as separate units and the CIP-scale evaluates the implant system as a whole, as recommended earlier (Mau, 1993) The first is of interest to answer

questions with regard to the success of the individual implants; the latter gives more insight in the total, surgical and prosthetic, success of an implant system. In this way comparison of completely different systems in randomized clinical trials is possible. Next to this the study itself demonstrates the feasibility of the Delphi method in evaluating dental procedures.

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A MULTICENTER CLINICAL TRIAL OF IMPLANT-RETAINED MANDIBULAR OVERDENTURES IN PATIENTS WITH SEVERELY RESORBED MANDIBLES; CLINICAL ASPECTS.

A randomized clinical trial

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ABSTRACT

In a multicenter clinical trial treatment effects of overdentures on different implant systems in patients with severely resorbed mandibles were compared one year after insertion of the new dentures The implant-systems used were the transmandibular implant- (TMI), the IMZ- (IMZ) and the Brånemark-system (BRÅ) Treatment was randomly assigned to 88 patients according to a balanced allocation method Evaluation included peri-implant and radiographic parameters According to the Delphi-method a Clinical Implant Performance scale (CIP) was constructed based on all conceivable complications of the different implant-systems During the healing period one IMZ- and one BRÅ-implant were lost One TMI was removed after functional loading The results of the peri-implant and radiographic parameters showed no significant differences between the three implant-systems

INTRODUCTION

A high rate of success has been documented for osseointegrated implants supporting fixed prostheses in edentulous jaws (Albrektsson *et al*, 1988,Adell *et al*, 1990) However, reports about implant-retained mandibular overdentures are scarce and have been presented only in recent years (Engquist *et al*, 1988, Gotfredsen *et al*, 1993, Mericske-Stern and Zarb, 1993, Batenburg *et al*, 1994, Mericske-Stern *et al*, 1994, Naert *et al*, 1994) The results seem to be comparable with those of implants supporting fixed prostheses Most studies do not report on patients with severely resorbed alveolar ridges A maximum height of the alveolar ridge as an inclusion criterion is almost never mentioned, only a minimum height requested for implantation

Few studies have been published in which different implant systems retaining overdentures were compared Lack of identical evaluation criteria and differences in selection criteria and patients' characteristics make comparison of studies in which only one implant system is used impossible The only study design that enables comparison of different implant systems is a clinical trial In spite of recommendations to perform phase-III randomized clinical trials (Quayle, 1988, Meinert, 1990, Fiorellini and Weber, 1994) this study design is seldom applied

This study is part of a multicenter randomized clinical trial in which treatment effects of different implant systems retaining mandibular overdentures in patients with severely resorbed mandibles are compared with each other and with a control treatment, e.g. complete conventional dentures. Patient related as well as clinical aspects are evaluated. The results of patient related aspects were presented in a previous article (Boerrigter *et al*, 1994). This study compared clinical and radiographic aspects of different implant systems (retaining mandibular overdentures) in patients with severely resorbed mandibular alveolar ridges 1 year after insertion of the new overdentures. The implant systems used were the transmandibular implant- (**TMI**), the IMZ- (**IMZ**) and the Brånemark-system (**BRÅ**). Clinical aspects include criteria to evaluate the peri-implant tissues and criteria to evaluate the mandibular overdentures retained by the different implant systems.

MATERIAL AND METHODS

Patient selection and study design

For this clinical trial edentulous patients with severely resorbed mandibles and persistent problems wearing conventional complete dentures were selected. Two centers participated in this study, e.g. the Department of Oral and Maxillofacial Surgery and Maxillofacial Prosthodontics (University Hospital Groningen) and the Department of Oral Function and Prosthetic Dentistry and the Department of Oral and Maxillofacial Surgery (University of Nijmegen). The criteria for inclusion were: a mandibular symphyseal bone height of 8-15 mm as measured on a standardized lateral cephalogram, no history of preprosthetic surgery or implant treatment and no general medical contra-indications for implants or a surgical procedure. All subjects were informed about the different treatment options, possible risks and the method used for treatment assignment. Written informed consent was obtained from all participating patients.

Treatment was randomly assigned using a balancing procedure (Zielhuis *et al*, 1990), aiming at an equal distribution of patients over the treatment groups with regard to variables that may interfere with the outcome of the study (balancing criteria). In this trial the criteria were age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphyseal

bone height of the mandible The study design is described in full detail in a previous article (Geertman *et al*, 1994)

In the period of november 1989 until september 1991 157 patients were selected and treatment was randomly allocated Implant-retained overdenture treatment was allocated to 93 patients and complete denture treatment to 64 patients As this article deals with clinical aspects of different implant systems the results of the 'complete denture group' will not be presented Five patients refused implant-treatment, so the total group consisted of 88 patients at baseline Table 4 2 1 shows that 58 of these patients were treated with permucosal implants (41 IMZ and 17 Brånemark) and 30 with a transmandibular implant Characteristics of the patients are presented in table 4 2 2 The comparability of all groups was tested before treatment for these variables, no significant differences were found (2-way ANOVA) The group consisted of 69 women and 19 men, their age varied from 35 to 84 years, with an average of 54 years

Table 4.2.1 Number of participants in the trial

Center	**Transmandibular implants**	**Permucosal implants**		**Total**
	TMI	**IMZ**	**BRÅ**	
Nijmegen	30	29	0	59
Groningen	0	12	17	29
	30	41	17	88

Table 4.2.2 Patient characteristics {mean (sd) or percentages (%)}

		(n=88)
Age in years (sd)[1]		54 (9)
Gender[1]	Men (%)	21
	Women (%)	79
Edentulous period mandible in years[1]		22 (8)
Edentulous period maxilla in years		24 (9)
Number of mandibular dentures[1]		3 (1.5)
Number of maxillary dentures		3 (1.5)
Age present mandibular denture[1]		6 (5)
Age present maxillary denture		7 (5)
Mandibular bone height in mm[1]		13.6 (1.5)

[1] Balancing-criteria

Table 4.2.3 Freqencies of the post / implant length of the transmandibular implant (n=119) and of the IMZ (diameter 3.3 mm n=12; 4.0 mm n=70) and Brånemark implants (diameter 3.75 mm)

		post length (in mm)					
TMI		**8**	**10**	**12**	**14**	**16**	**18**
Number of posts		4	26	44	29	15	1
		implant length					**Total**
		7	**8**	**10**	**11**	**13**	
IMZ	**3.3 and 4.0 mm**	-	19	8	34	21	82
BRÅ	**3.75mm**	8	-	16	0	10	34
Total		8	19	24	34	31	116

Treatment procedures

The transmandibular implant according to Bosker (fig. 4.2.1; Krijnen Medical BV, Beesd, the Netherlands; Bosker, 1986) was inserted under general anaesthesia; the distribution of the lengths of the posts is presented in table 4.2.3. The day after surgery the superstructure was placed, consisting of a triple-bar construction with two cantilever extensions. During a period of three months patients were not allowed to eat solid food nor to wear the mandibular denture. After this period the manufacturing of the new maxillary denture and the mandibular overdenture was started.

In case of permucosal implants according to the IMZ-system (fig. 4.2.2, Friedrichsfeld AG, Mannheim, Germany; Kirsch and Mentag, 1986) and the Brånemark-system (fig. 4.2.3; Nobelpharma AB, Goteborg, Sweden; Brånemark *et al*, 1985) two implants were interforaminally inserted in the mandible under local anaesthesia, the distribution of the lengths of the implants is also presented in table 4.2.3. Patients were not allowed to wear the mandibular denture during the first two weeks after surgery. After initial woundhealing the denture was adjusted with a soft-liner and a soft diet was prescribed. After three months the second stage surgery was performed (i.e. abutment connection) and the manufacturing of the new maxillary denture and mandibular overdenture was started. The overdentures were supported by a single bar-clip attachment.

In all treatment groups the dentures were manufactured with an optimal fit and according to the balanced occlusion principle.

Figure 4.2.1a A transmandibular implant according to Bosker

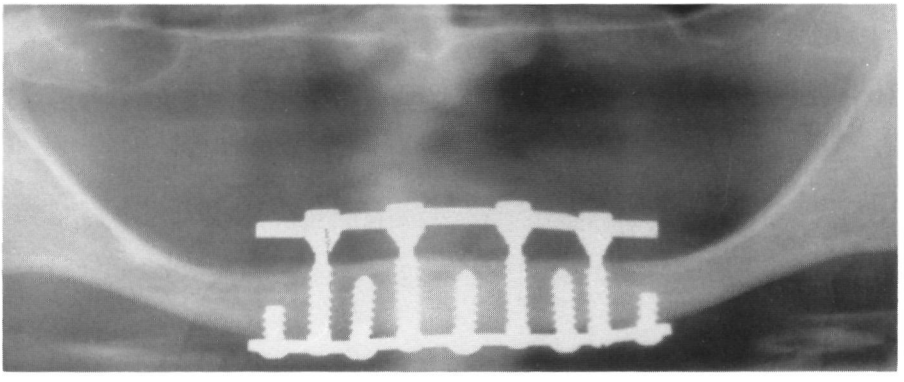


Figure 4.2.1b A transmandibular implant according to Bosker

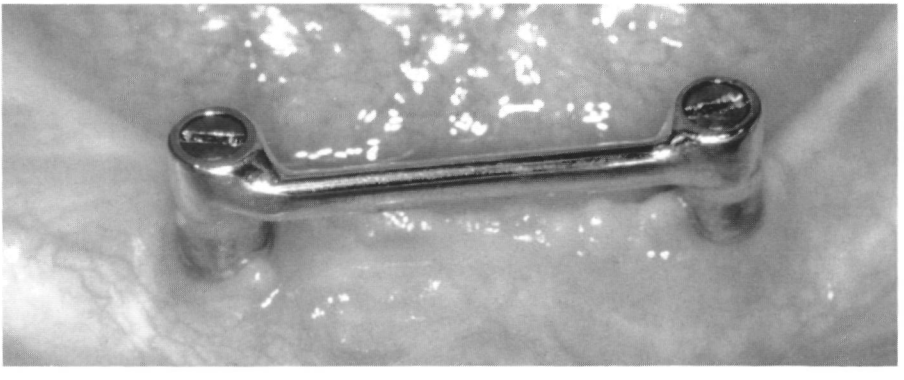


Figure 4.2.2a Two IMZ implants with a bar

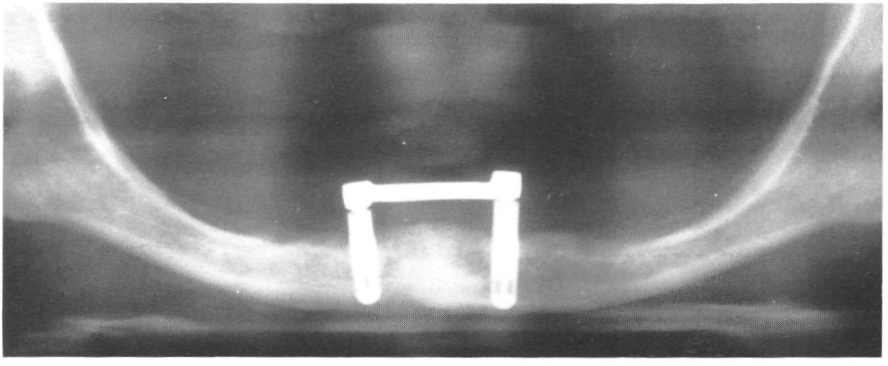


Figure 4.2.2b Two IMZ implants with a bar

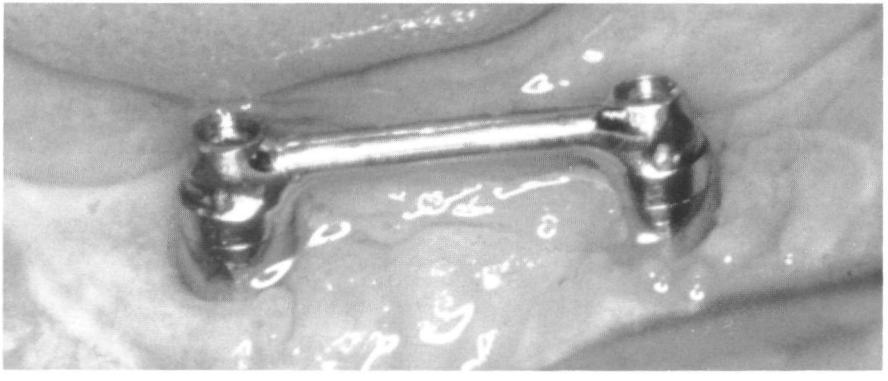


Figure 4.2.3a Two Brånemark implants with a bar

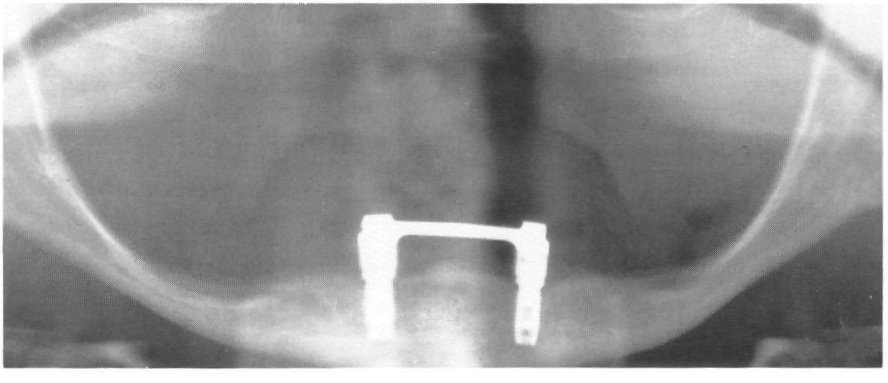


Figure 4.2.3b Two Brånemark implants with a bar

Data collection

Peri-implant parameters - The Plaque Index (**PI**) according to Mombelli *et al* (1987), Bleeding Index (**BI**) according to Mombelli *et al* (1987) and the Gingiva Index (**GI**) according to Loe & Silness (1963) were used Probing depth (**PD**) was assessed at 4 locations around each implant or post (mesially, buccally, distally and lingually) with a Meritt-B, Hu Friedy™ periodontal probe Keratinized mucosa (**KM**) was assessed at two sites around each abutment (buccally and lingually) according to Apse *et al* (1991)

Radiographic evaluation Orthopantomographic radiographs (OPT) were made immediately after surgery and one year after the insertion of the new dentures The marginal bone height was evaluated both mesially and distally of the implant The radiographs one year after insertion of the new dentures were compared with the radiographs immediately after surgery and classified on a four point rating scale (0-3)

0 = No apparent bone loss
1 = Reduction of the bone level not exceeding more than 1/3 of the implant length
2 = Reduction of the bone level exceeding 1/3 of the implant length but not exceeding 1/2 of the implant length
3 = Reduction of the bone level exceeding 1/2 of the implant length

Clinical Implant Performance scale (CIP-scale)

In order to be able to compare the results of the different implant systems all surgical, prosthetic, radiographic and peri-implant complications, that occurred from the day the manufacturing of the new dentures started till one year after insertion, were taken into account With these data a Clinical Implant Perform ance scale (CIP-scale) was constructed according to the Delphi-method

The Delphi-method is a method to obtain consensus in questions that are issues of uncertainty even to experts described by Milholland et al (1973) For this study all conceivable complications that might occur after placement of dental implants were written down and presented to six experts They were asked to rate their opinion anonymously for each complication on a five point rating scale When differences in opinion occurred they were asked to rate their

opinion again, knowing the scores of the other experts After three rounds there was almost complete agreement on 88% of the items ('almost' means agreement of at least five of the six experts) The principles of the Delphi-method and the construction of this CIP-scale were previously described by Van Waas *et al* (1995)

The CIP scale consisted of a five point rating scale (0-4)

0 = Success, no complications
1 = Minor complications that do not need intervention or are easily treated
2 = Complications with a chance on recovery or stabilization of the present situation
3 = Serious complications which may lead to failure of the implant system
4 = Failure of the implant system

Minor complications (CIP=1) were gingival hyperplasia, relining of maxillary or mandibular denture, readjustment of occlusion and articulation, clip loosening, fracture of a cantilever extension (TMI), coping screw loosening (IMZ/BRÅ), broken abutment (IMZ/BRÅ), a slight sensory disturbance of the mental nerve, X-ray score 0 along with PD≥5 5 mm X-ray score 1 along with PD<5 5 mm

Complications with a chance on recovery or stabilization of the present situation (CIP=2) were correction of a not fitting superstructure, fracture of the superstructure, a severe sensory disturbance of the mental nerve, fracture of one post (TMI), X-ray score 1 along with PD≥5 5 mm or X ray score 2 along with PD<5 5 mm

Serious complications (CIP=3) were scored if one or two posts were mobile (TMI), in case of removal of one post (TMI), a X-ray score 2 along with PD≥5 5 mm or a X-ray score 3

Failure of the implant system (CIP=4) was scored in case of removal of two or more posts (TMI) or removal of one (or two) implant(s) (BRÅ/IMZ)

Interobservers agreement

Before measuring was started the criteria for the clinical and radiographic parameters were evaluated. In each center 2 observers were selected for the 1-year evaluation. Several times observers were exchanged between the 2 centers as a control of the standard protocol. Inter observers agreement was determined by means of Cohen's kappa. Kappa represents the observed proportion of nonchance agreement. The Cohen's kappa's for the Plaque index was 0.57, the Bleeding index 0.44, Gingiva index 0.54 and Keratinized Mucosa 0.67.

Statistical analysis

Differences between the treatment groups before treatment and between the implant systems at the 1-year evaluation were tested at patient level, i.e. the mean patient values were analysed. A two-way ANOVA was used according to treatment and center to correct for possible confounding, followed by multiple comparison.

RESULTS

The comparability of all groups was tested before treatment for the variables of table 4 2 2 No significant differences were found (2-way ANOVA, logistic regression for gender) During the healing period before loading, two failures were observed one Brånemark implant and one IMZ implant Both implants were replaced after bone healing Three months after placement they were functionally loaded and remained successfully in function

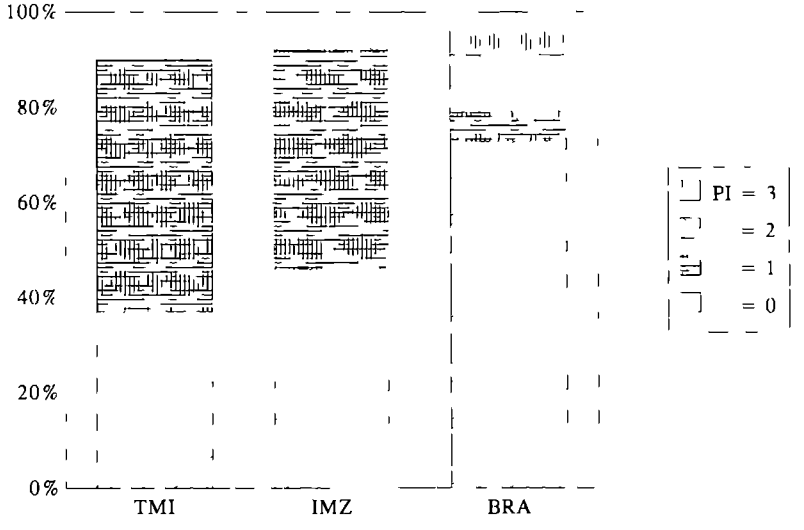
During the first year after insertion of the new dentures one transmandibular implant was lost The implant had to be removed due to mobility of three of the four posts Two posts of another transmandibular implant were removed due to mobility, the remaining posts were left in situ At the 1-year evaluation two patients of the TMI-group were lost to follow-up one was not satisfied with her facial appearance and refused any further cooperation, the other did not show up at the appointments several times Since 3 patients of the TMI-group did not participate in the one year evaluation 27 patients remained No patients were lost to follow-up in the IMZ- and the BRÅ-group

Peri-implant parameters

The mean scores of two observers for all peri-implant parameters are used in subsequent analyses Either four posts of the transmandibular implant or two IMZ or two Brånemark implants are presented in the graphs This means that n is 105 for the TMI-group, 82 for the IMZ-group and 34 for the BRÅ-group

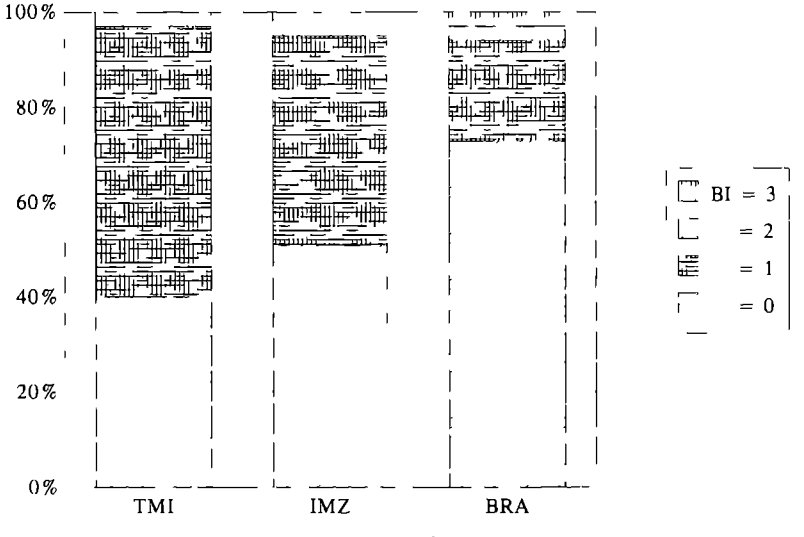
The frequency distribution of implants/posts with(out) plaque is presented in figure 4 2 4 The mean value was 0 5 (TMI), 0 5 (IMZ) and 0 6 (BRÅ) The differences between the implant systems were not significant (2-way ANOVA)

The corresponding values for the Bleeding index were 0 4, 0 4 and 0 3 respectively, the differences were not significant (2-way ANOVA) The frequency distribution is presented in figure 4 2 5



TMI n=105 IMZ n=82, BRÅ n=34 (implants/posts)

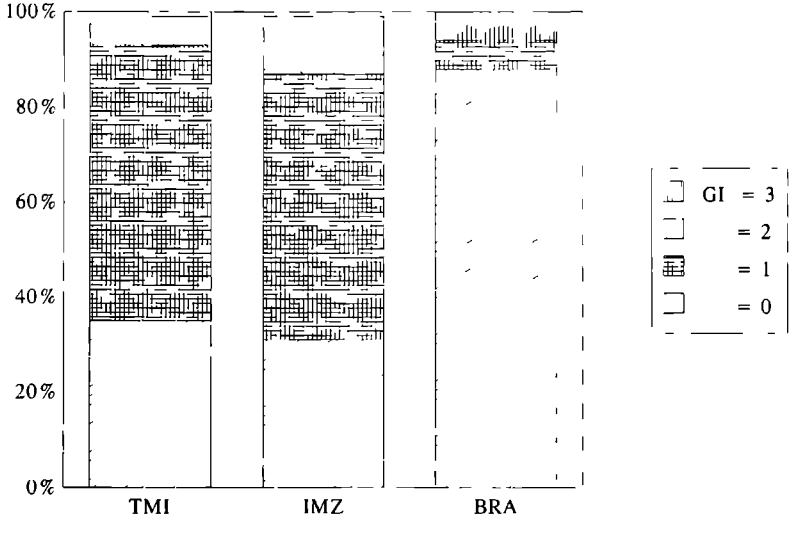
Figure 4.2.4 Plaque Index



TMI n=105, IMZ n=82, BRÅ n=34 (implants/posts)

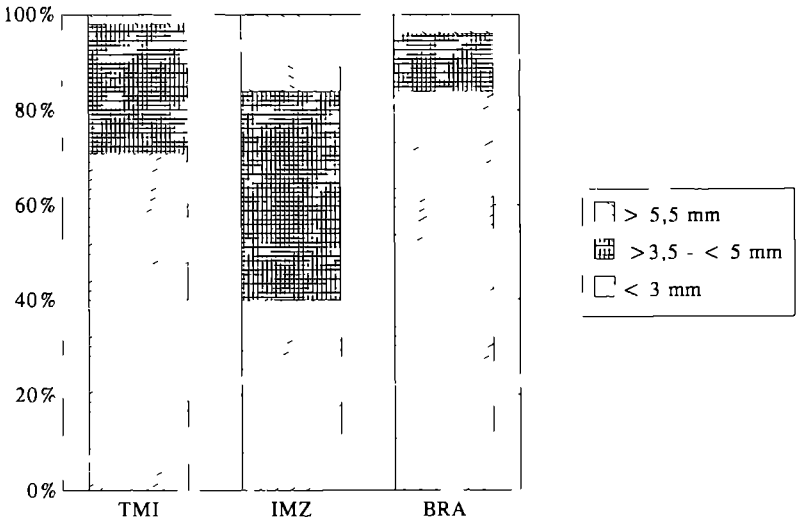
Figure 4.2.5 Bleeding Index

The frequency of gingival inflammation around the implants/posts is shown in figure 4.2.6. The mean values were 0.5 (TMI), 0.7 (IMZ) and 0 2 (BRÅ). The differences between the IMZ- and the BRÅ-group were significant, the differences between TMI-IMZ and TMI-BRÅ were not significant (2-way ANOVA) The frequency distributions of the probing depths in the ranges 0-3 mm, 3 5-5 mm and 5.5 mm or more are presented in figure 4.2.7. The mean probing depth (4 measurements per implant/post) for the TMI-group was 3.0 mm (sd 0.4), for the IMZ-group 3.7 mm (sd 0.9) and for the BRÅ-group 2.5 mm (sd 0 8). Differences between IMZ-BRÅ and IMZ-TMI were significant, differences between TMI-BRÅ were not significant (2-way ANOVA). Gingiva index and probing depth showed significant differences among the implant systems, while no center differences were found (2-way ANOVA). The assessments of the width of keratinized mucosa on the buccal and lingual sites (fig. 4.2.8) show that 10% of the posts of the TMI-group, 10% of the implants of the IMZ-group and 23% of the BRÅ-group were not surrounded by a zone of keratinized mucosa.



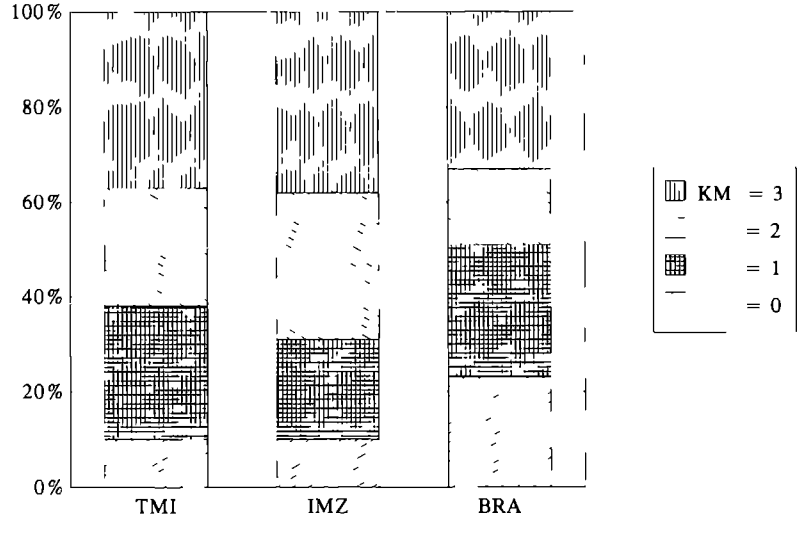
TMI n=105, IMZ n=82, BRÅ n=34 (implants/posts)

Figure 4.2.6 Gingiva Index



TMI n=420, IMZ n=328, BRÅ n=136

Figure 4.2.7 Probing depth



TMI n=210, IMZ n=164, BRÅ n=64, 0=no keratinized mucosa, 1=1 mm or less of keratinized mucosa, 2=between 1 and 2 mm of keratinized mucosa, 3=more than 2 mm of keratinized mucosa

Figure 4.2.8 Keratinized mucosa

Radiographic evaluation

Table 4.2.4 shows the bone level changes one year after insertion of the new dentures. Of each implant/post the most unfavourable value of the two measurements was used. No apparent bone loss was reported in 46% of the TMI-posts, 59% of the IMZ- and 32% of the BRÅ-implants. Reduction of the bone level exceeding 1/3 of the implant length was reported in 8% of the TMI-posts, 8% of the IMZ- and 3% of the BRÅ-implants. The mean scores for the TMI-group was 1.0 (sd 0.6), for the IMZ-group 0.7 (sd 0.8) and for the BRÅ-group 0.9 (sd 0.5). Differences between the three systems were not significant (2-way ANOVA).

Table 4.2.4 Frequencies of the bone level reduction (in percentages) one year after insertion of the new dentures

	n	0*	1	2	3
TMI	105	46	46	5	3
IMZ	80	59	32	7	2
BRÅ	34	32	65	3	0

* 0 = no apparent bone loss, 1 = reduction < 1/3 of the implant length, 2 = reduction > 1/3, < 1/2 of the implant length, 3 = reduction > 1/2 of the implant length

Clinical Implant Performance scale

Figure 4.2.9 shows that only 7% of the TMI patients, 29% of the IMZ patients and 12% of the BRÅ patients did not have complications (CIP=0). The majority of the complications were not serious (CIP=1). Peculiar to the TMI-group were fracture of a cantilever extension and a slight sensory disturbance of the mental nerve. Loosening of coping screws occurred only in the IMZ-group and replacement of the clip only in the BRÅ-group. Gingival hyperplasia was noted in the IMZ- and BRÅ-group, other complications that were carried out were relining of the maxillary denture and readjustment of occlusion and articulation.

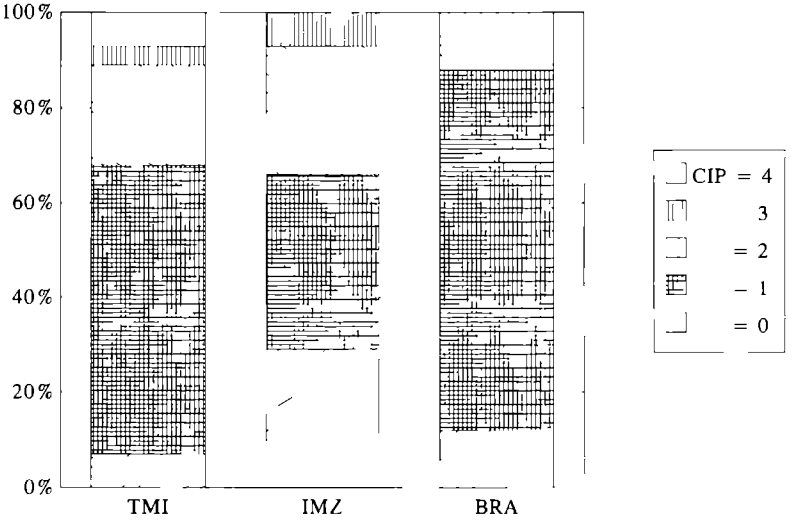
Fracture of a post (CIP=2), correction of a not fitting superstructure and a severe sensory disturbance were complications peculiar to the TMI-group. An

X-ray score 1 along with PD≥5 5 mm and X-ray score 2 along with PD<5 5 mm was noted in all groups

One mobile post (CIP=3) was noted in the TMI-group, other serious complications that occurred in the TMI- and the IMZ-group were X-ray score 2 along with PD≥5 5 mm and an X-ray score 3

Failure of the implant system (CIP=4) occurred twice in the TMI-group Removal of two posts was done in one patient, the remaining posts were left in situ and are still supporting the overdenture One implant was completely removed No failures were noted in the IMZ- and BRÅ-group

The mean CIP-scores for the different implant systems were 1 4 sd 1 0 (TMI), 1 1 sd 0 9 (IMZ) and 1 0 sd 0 5 (BRÅ) The differences between the implant systems were not significant (2-way ANOVA)



TMI n=28, IMZ n=41, BRÅ n=17 (n=patients)

Figure 4.2.9 Clinical Implant Performance scale

DISCUSSION

To our knowledge, this is the first publication of a randomized clinical trial in which different implant systems are compared Patients are randomly assigned (by a balancing procedure) to the different treatment groups Comparison of general characteristics at entry indicates that the balancing procedure provided three identical treatment groups Only in this way different implant-systems can be compared (Kapur and Garett, 1988)

In this study of patients with severe alveolar bone loss in the mandible the symphyseal bone height was chosen to be less than 15 mm, but more than 8 mm as measured on a standardized lateral cephalogram Often the symphyseal bone height is higher than the vertical dimension of the alveolar ridge in the canine-region, because the mental spine area keeps its height longer than other parts of the alveolar ridge Since the permucosal implants were inserted in the canine-region the bone height at that point was presumably less than the mean symphyseal bone height of 13 6 mm (table 4 2 2) This could be the explanation why the length of the permucosal implants was in majority 11 mm or less (73%) The length of the posts of the transmandibular implant do not account for the height of the mandibular ridge as the posts penetrate the mandible, part of it in the baseplate and sometimes threads towering over the alveolar ridge

The scores of the Plaque, Gingiva and Bleeding Index were favourable and seem to be comparable with those of studies on overdentures (Gotfredsen *et al*, 1993, Batenburg *et al*, 1994, Mericske-Stern *et al*, 1994, Naert *et al*, 1994, Quirynen *et al*, 1991) Comparison with these studies, however, is difficult as different criteria are used in these studies The results showed no significant differences for the Plaque and Bleeding Index between the implant systems The Gingiva Index showed significantly better scores for the BRÅ- than the IMZ-group

Differences in probing depth were significant between IMZ-BRÅ and IMZ-TMI Conclusions, however, should be drawn with caution as the geomet ric design of the three implant systems are not comparable The transmandibular implant has threaded posts, the IMZ-implants are cylinders with a smooth surface and the Brånemark implants are threaded cylinders The abutments of the IMZ- and BRÅ-system have also different geometric designs the IMZ abutment and implant body have the same width whereas the BRÅ-abutment is wider than

the implant body Measuring probing depth along the TMI posts and BRÅ implants is more difficult than along the IMZ-implants. This could probably be the reason that the mean probing depth of the IMZ implants is deeper (3 7 mm sd 0 9) than those of the other systems (TMI 3 0 mm sd 0 4, BRÅ 2 5 mm sd 0 8)

Orthopantomographic radiographs were used for the evaluation of the bone levels because of the difficulty of good parallel positioning of periapical films in patients with severe resorption and a pronounced floor of the mouth Furthermore, only part of the TMI system can be evaluated with periapical films As we wanted to use the same method for all implant systems OPT's were made of all patients The bone level changes were evaluated in proportion to the length of the implant This was done because absolute measurements (in millimetres) can not be done on an OPT as reproducibility with this technique is difficult to achieve

Small bony defects were detected in 46% of the TMI-posts, 32% of the IMZ- and 65% of the BRÅ-implants Comparing radiographs made directly after surgery and after one year of loading will often show some defects as the top the implants were placed flush with the marginal bone level, and the top of the IMZ and the BRÅ implants are highly polished Moreover, the first year of functioning includes the bone remodelling phase and subsequent years will exhibit a much lower rate of bone loss (Chaytor, 1993) The results of this study are of the first year of functioning, so minor bone level changes could be expected Furthermore, results would have been better when the mean scores were presented instead of the most unfavourable score of each implant/post, as averaging masks greater variations in individual measurements

The Clinical Implant Performance scale has been developed in order to be able to compare the different implant systems including all the complications that occurred So far many studies reported on survival rates (Adell *et al*, 1990, Engquist *et al*, 1988) The data of these studies only represent the percentages of implants that have not been removed The success-criteria of Smith & Zarb (1989) are much more specified but still have an absolute character of yes or no with respect to success or failure Albrektsson & Zarb (1993) have suggested that every implant should be evaluated as part of a four-grade scale representing 'success', 'survival', 'unaccounted for' and 'failure' We wanted to construct a scale that included not only the success criteria of Smith & Zarb (1989) and the

categories of Albrektsson & Zarb (1993), but all the complications that occurred in order to be able to compare the different implant systems

The differences in the mean scores of the three implant systems were not significant The TMI-group, however, displayed more complications than the other implant-groups, mainly surgical and prosthetic complications Two failures occurred one TMI had to be completely removed and two posts of another TMI The IMZ-group showed mainly radiographic complications along with PD $>$ 5 5 mm and few surgical and prosthetic complications The BRÅ-group showed mainly minor radiographic complications However, one IMZ- and one BRÅ-implant were removed during the healing period These failures were not part of the CIP-scale as all complications that occurred from the day the manufacturing of the new dentures started till one year after insertion, were taken into account The score CIP=3, which means a serious complication which may lead to failure of the implant, was given to three patients because of an X-ray score 2 along with PD $\geq$5 5 mm or an X-ray score 3

This study is the first attempt at comparison of clinical and radiographic performances of three different implant systems in a clinical trial The results do not reveal significant differences at the evaluation one year after insertion of the new implant-retained overdentures To assess the clinical differences between the three implant systems in patients with severely resorbed mandibles long-term evaluation is necessary

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CHAPTER 5

DENTURE SATISFACTION IN A COMPARATIVE STUDY OF IMPLANT-RETAINED MANDIBULAR OVERDENTURES.

A randomized clinical trial.

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ABSTRACT

The aim of this study was to compare the experiences with surgical procedures and the treatment effects of a mainly implant supported overdenture, retained by a transmandibular implant according to Bosker (**TMI**), with those of an implant-tissue supported overdenture, retained by two IMZ implants (**IMZ**) Treatment had been assigned according to a balanced allocation method to 95 patients, including a control group who received only complete dentures Since some of the patients refused the allocated treatment the 'Intention To Treat' analysis was applied The results show that the experiences with surgical procedures were significantly more positive for the TMI-group than the IMZ-group The differences with respect to satisfaction, complaints and subjective chewing ability were not significant These results were unexpected as the overdentures retained by the transmandibular implant were to a much larger extent supported by the implant than the overdentures retained by 2 IMZ implants

INTRODUCTION

Considerable research has been done on the efficacy of dental implants, mainly in the areas of biocompatibility of the implant material, osseointegration, implant design and clinical success-rates However, few studies have been carried out to evaluate the surplus value of implant treatment compared to a conventional treatment method in which the patients' views are taken into account Some studies have been published concerning fixed mandibular implant-retained prostheses Satisfaction is generally high (Blomberg and Lindquist, 1983, Hoogstraten and Lamers, 1987, Kiyak *et al*, 1990) Blomberg and Lindquist studied patients' reactions before and after placement of the prostheses the majority of them reported improvement of their quality of life, regained self-confidence and acceptance of the prosthesis as a part of themselves Hoogstraten and Lamers compared satisfaction of patients with fixed prostheses to satisfaction of patients with complete dentures Results showed that the patients with fixed prostheses were much more satisfied Kiyak *et al* conducted a longitudinal study to assess the psychological impact of dental implants at different stages in treatment, satisfaction was high

Concerning implant-retained overdentures few studies have been published, and up till now no study has been published in which implant-tissue supported overdentures were compared to mainly implant supported overdentures. Clancy *et al* (1991) Wismeijer *et al* (1992) evaluated patients treated with implant-retained mandibular overdentures on 4 or more implants, using respectively CoreVent implants and one stage TPS-implants. Results showed that the vast majority of the patients was satisfied with their overdenture. Corresponding results were found by Van Waas and Bosker (1989). However these studies did not compare different implant systems nor implant treatment to a control group.

The aim of the present study was to compare the experiences with surgical procedures and the treatment effects of a mainly implant supported overdenture, retained by a transmandibular implant according to Bosker (**TMI**), with those of an implant-tissue supported overdenture, retained by two IMZ implants (**IMZ**). It is part of a multicenter randomized clinical trial in which treatment effects of implant-retained mandibular overdentures, using different implant-systems, were compared with the effects of new conventional complete dentures. The comparison of implant treatment with conventional complete denture treatment is presented elsewhere (Boerrigter *et al*, 1995). This part of the study concentrates on the TMI-IMZ comparison, the results of the conventional complete denture treatment (**CD**) are only presented as a reference.

MATERIAL AND METHODS

Patient selection

The subjects selected for this study were edentulous patients with a severely resorbed mandible and persistent problems wearing conventional complete dentures. They were referred by general practitioners to the University of Nijmegen, Department of Oral Function and Prosthetic Dentistry and the Department of Oral and Maxillofacial Surgery, and were screened for their eligibility by a prosthodontist and an oral surgeon. The criteria for inclusion were (1) a mandibular symphyseal bone height of 8-15 mm as measured on a standardized lateral cephalogram, (2) no history of preprosthetic surgery or implant treatment, (3) no general medical contra-indications for implant treatment.

Treatment groups

Treatment was carried out according to routine, protocolled procedures. For all patients a new maxillary denture was manufactured. With respect to the mandibular denture three different treatment modalities were applied: one group received a mainly implant supported overdenture retained by a transmandibular implant (fig. 5.1; Krijnen Medical BV, Beesd, the Netherlands; Bosker, 1986), the second group received an implant-tissue supported overdenture on two IMZ implants (fig. 5.2; Friedrichsfeld AG, Mannheim, Germany; Kirsch and Mentag, 1986) and the third group received a completely mucosa supported conventional denture.

The transmandibular implant was installed under general anaesthesia, the day after surgery the superstructure was placed: a triple Dolderbar construction with cantilever extensions. Patients were not allowed to eat solid food, nor to wear their mandibular denture for a period of three months. The mandibular overdenture was retained by 5 clips on the superstructure.

The two IMZ implants were interforaminally installed under local anaesthesia, in combination with an Edlan-Mejchar vestibuloplasty. A soft diet was prescribed and 2 weeks after surgery the mandibular denture was adjusted with a softliner. After a healing period of three months the second stage surgery (i.e. abutment connection) was performed. The mandibular overdenture was retained by a single clip attachment on a Dolderbar. The CD-group received just a new set of dentures.

In all treatment groups porcelain teeth had been used, designed and arranged according to the lingualized occlusion concept (Becker *et al*, 1977; Lang and Razzoung, 1992; Optiform, ENTA-Lactona, Bergen op Zoom, The Netherlands).

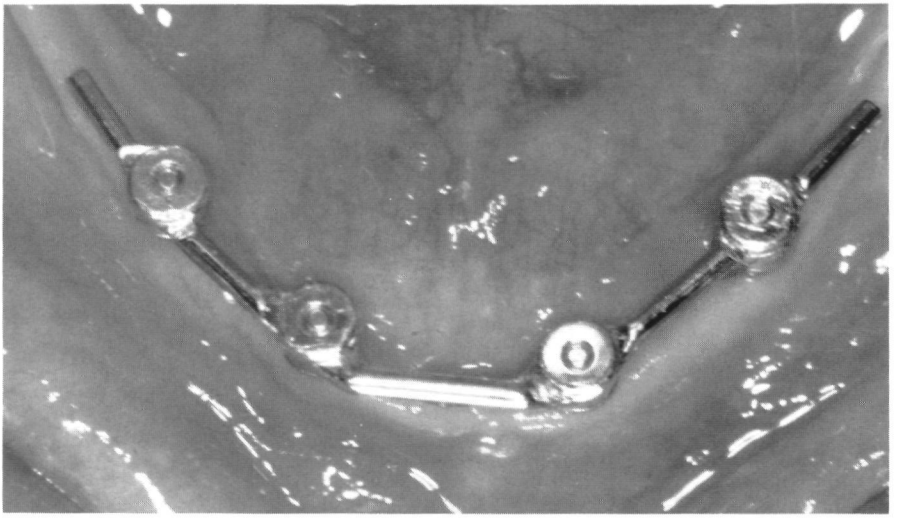

Figure 5.1a The transmandibular implant

Figure 5.1b A mainly implant supported overdenture

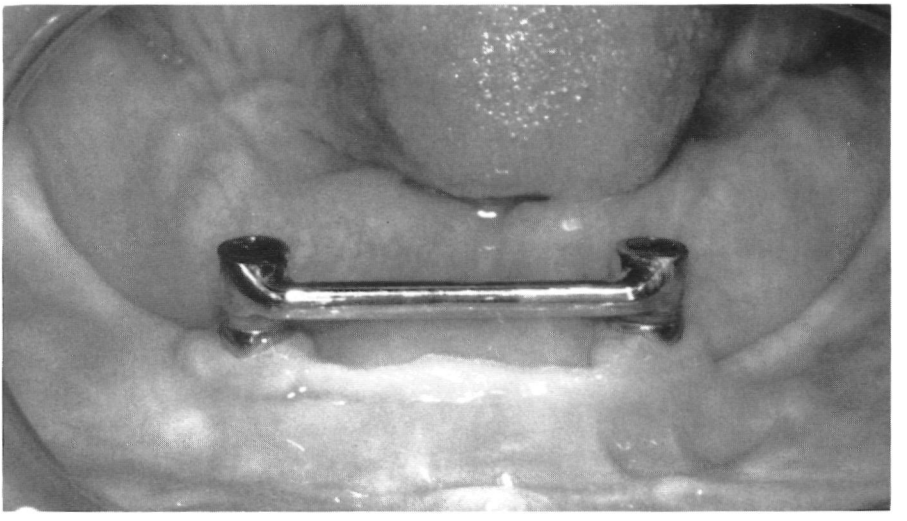

Figure 5.2a Two IMZ implants with a Dolderbar

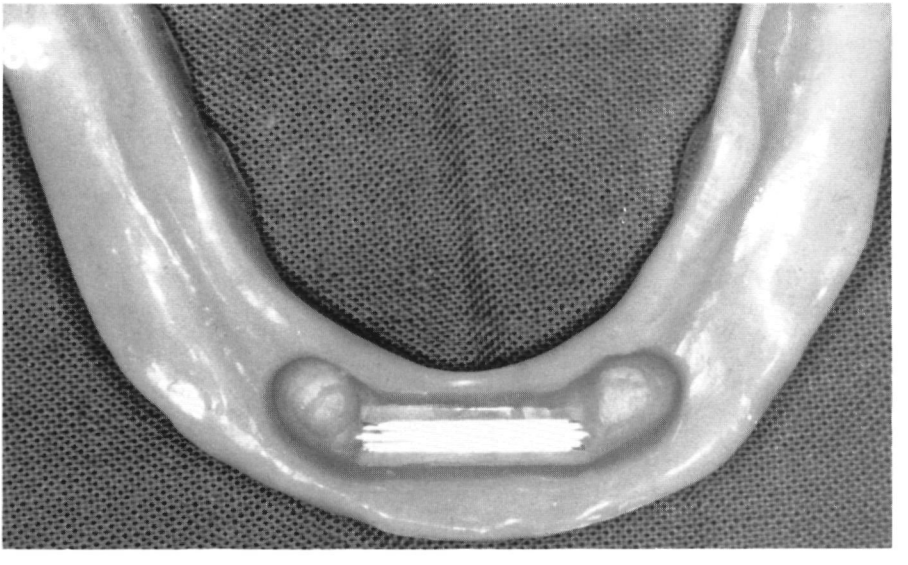

Figure 5.2b An implant-tissue supported overdenture

Study design and treatment assignment

The ethical committee of the faculty of Medical Sciences gave approval for a randomized clinical trial, i e eligible patients were asked to give their written consent for participation in the trial Since some of the patients refused treatment after allocation the 'Intention To Treat' principle was applied (Lee *et al*, 1991, Antczak-Bouckoms and Chalmers, 1988) This implies that patients are evaluated in the originally allocated treatment group regardless the actual treatment they received Treatment was allocated using a balancing procedure (Zielhuis *et al*, 1990), aiming at an equal distribution of the patients over the treatment groups regarding variables that may interfere with the outcome of the study (balancing criteria) In this trial the criteria were age, gender, the edentulous period of the mandible, the number of previously made mandibular dentures, the number of years having worn the present mandibular denture and the symphyseal bone height of the mandible A computer-program was used for the allocation of patients to the treatment groups

Treatment was allocated to 95 patients Table 5 1 shows that 85 patients treated according to allocation and six patients who refused the allocated treatment were part of the 'Intention To Treat' analysis Four patients were lost to follow-up one year after insertion of the new dentures The distribution over the three treatment groups was as follows At the baseline the TMI-group consisted of 31 patients 30 of them received a mandibular implant-retained overdenture and one patient refused the allocated treatment This patient did not want surgery and did not ask for other treatment During the first year after insertion of the new dentures one implant was removed At the 1-year evaluation two patients were lost to follow-up one did not show up several times at the appointments and the other was dissatisfied with her facial appearance and refused any further cooperation The IMZ-group consisted of 33 patients at the baseline 29 of them received a mandibular implant-retained overdenture and four patients refused the allocated treatment They did not want surgery and did not ask for other treatment One year after insertion of the new dentures no patients were lost to follow-up The CD-group consisted of 31 patients at the baseline Thirty of them received a conventional complete denture and one refused the allocated treatment He wanted implants and received this treatment At the one year evaluation two patients were lost to follow-up one patient had moved and the

treatment of the other patient was never finished, she refused any further cooperation.

Table 5.1 Patients treated or not treated according to allocation

	Treatment according to allocation		Treatment not according to allocation		Total		
	baseline	1 year	baseline	1 year	baseline	dropout	1 year
TMI	30	28	1	1	**31**	2	**29**
IMZ	29	29	4	4	**33**	0	**33**
CD	30	28	1	1	**31**	2	**29**
Total	89	85	6	6	**95**	4	**91***

* subjected to 'Intention to Treat' analysis

Table 5.2 Patients' characteristics at the baseline (mean (sd) or percentages (%))

	TMI n=29	IMZ n=33	CD n=29
Age in years[1] (SD)	53 (10)	53 (8)	55 (9)
Gender[1] Male (%)	24	18	28
Female (%)	76	82	72
Edentulous period mandible in yrs[1] (SD)	21 (8)	21 (8)	24 (9)
Edentulous period maxilla in yrs [1] (SD)	25 (8)	24 (9)	27 (9)
Number of mandibular dentures[1] (SD)	4 (2)	3 (1)	3 (1)
Number of maxillary dentures[1] (SD)	4 (2)	3 (1)	4 (1)
Age present mandibular denture[1] (SD)	6 (5)	7 (5)	6 (4)
Age present maxillary denture (SD)	6 (5)	7 (5)	6 (4)
Mandibular bone height in mm[1] (SD)	13.7 (1.4)	13.8 (1.3)	13.6 (1.3)

[1] Balancing criteria

The evaluated group consisted of 70 females and 21 males They varied from 36 to 75 years of age, with an average of 54 years (sd 9 years) They had been edentulous for an average of 22 years, and had received three prostheses on average before treatment was started The characteristics and balancing criteria are presented in table 5 2 No significant differences were found between the treatment-groups

Evaluation criteria

- Experiences with surgical procedures One week after surgery the patients of both implant groups were asked to express their opinion about the surgical procedure This was repeated for the IMZ-group after the second stage surgery
- Satisfaction Patients' opinions were assessed by means of questionnaires with precoded response categories prior to treatment and one year after insertion of the new dentures The following aspects were evaluated
- Denture satisfaction This questionnaire consisted of nine items about the function of the dentures in general and maxillary and mandibular denture separately Each item could be answered on a three point rating scale (1 = satisfied, 2 = neutral, 3 = dissatisfied)
- Overall denture satisfaction, expressed on a discontinuous analog scale (1-10)
- Denture complaints (Vervoorn *et al*, 1988) This questionnaire consisted of 54 items Each item could be answered on a 4 point rating scale (0 = no complaints, 1 = little, 2 = moderate, 3 = severe complaints) Factor- and reliability analyses were carried out On the initial scores six factors appeared functional complaints mandibular denture (e g 'lower denture gets loose during speaking'), functional complaints maxillary denture (e g 'upper denture gets loose during eating'), functional complaints in general (e g 'full sensation due to the denture'), physiognomy (e g 'mouth has fallen-in'), 'neutral space' (e g 'lip or cheek biting'), aesthetics (e g 'teeth are too big') The reliability coefficients Cronbachs' α for all factors appeared to be quite satisfactory, ranging from 0 76 to 0 90 (table 5 3) Cronbach's α may be interpreted as the correlation coefficient between the measured variable and the true variable (Cronbach, 1951) One year after insertion of the new dentures the scale structure was checked No changes in the originally constructed scales were necessary The

scale 'aesthetics' is left out in further analysis because it did not vary after treatment: all patients were satisfied with the appearance of the dentures.
- Chewing ability, assessed by questions about eight different types of food. The items could be answered on a three point rating scale (0 = good, 1 = moderate, 2 = bad). Factor- and reliability analyses were carried out. On the initial scores three factors appeared (table 5.3): 'soft food' (e.g. vegetables), 'tough food' (e.g. steak, cheese), 'hard food' (e.g. apple, carrot). The reliability coefficients Cronbachs' α are presented in table 5.3. One year after treatment the scale structure was checked, no changes in the originally constructed scales were necessary. The scale 'soft food' is left out in further analysis because it did not vary after treatment: all patients were able to eat soft food.

Table 5.3 Characteristics of the scales of the denture complaints and chewing ability questionnaire

	Number of items	**Cronbach's α**
Denture-complaints		
Functional complaints lower denture	12	0.90
Functional complaints upper denture	7	0.86
Functional complaints in general	7	0.76
Physiognomy	3	0.87
'Neutral space'	3	0.77
Aesthetics of the dentures	3	0.79
Chewing ability		
Soft food	3	0.81
Tough food	3	0.80
Hard food	2	0.84

Statistical analysis

Differences between both implant groups were tested by means of the Student's t-test and the Chi-square test with a significance level of 0.05. The data obtained at the one year evaluation were used to analyze the differences between the groups. The data of the denture satisfaction questionnaire and the data of the CD-group are presented as a reference.

RESULTS

Surgical procedures

Table 5.4 shows that 90% of the TMI-group answered the surgical procedure was better than they had expected, for 3% it fell short of expectations, the rest was neutral. For the IMZ-group it was 18%, 64% and 18% respectively. These differences were significant. The experiences with the second stage surgery (only IMZ) were more positive. 76% of the patients answered that it was better than expected.

Table 5.4 Percentages of the answers to questions about the experiences with surgical procedures 1 week after surgery

	Group	yes	neutral	no	Significance[1]
Was the surgery better than expected?	TMI	90	7	3	
	IMZ	64	18	18	*
Were you in good health ?	TMI	83	-	17	
	IMZ	82	-	18	N.S.
Did you have post-operative pain?	TMI	66	-	35	
	IMZ	82	-	18	N.S.
Did you use analgesics ?	TMI	31	-	69	
	IMZ	79	-	21	*
Did you feel uncomfortable not wearing your lower denture?	TMI	48	17	35	
	IMZ	54	18	29	N.S.

[1] Chi-square test; $p < 0.05$

Pre-treatment comparison and treatment outcome

No significant differences between the treatment groups were found for the patients characteristics prior to treatment. Almost all patients were not satisfied with their mandibular denture (table 5.5). It lacked retention and often caused pain. With respect to the maxillary denture two-thirds of the patients was satisfied. The general satisfaction rates given in all groups were about a 4 to 4.5 which indicates insufficiency. The same results were found for the scales of the complaint questionnaire and the chewing ability scales.

One year after insertion of the new dentures the TMI-group as well as the IMZ-group was satisfied in all aspects (table 5.5). Of the CD-group one third was satisfied, one third neutral and one third dissatisfied with their mandibular denture. The mean overall satisfaction rate of the TMI- and the IMZ-group was high (8.4 and 8.2), for the CD-group it was lower (6.7). With respect to the denture complaint scales the differences between the TMI- and the IMZ-group were not significant for any scale (table 5.6). The TMI- and the IMZ-group showed significantly better scores than the CD-group on the scales 'functional complaints mandibular denture', 'functional complaints in general' and 'neutral space'. The scales 'functional complaints maxillary denture' and 'physiognomy' did not differ significantly between all treatment groups. Regarding the chewing ability scales the treatment effect was similar: no significant differences between the TMI- and the IMZ-group; significant differences between the implant-retained groups and the CD-group.

Table 5.5 Distribution in percentages of answers on the denture satisfaction questionnaire pre-treatment and one year after insertion of the new dentures

		Pre-treatment	1 year after treatment		
			TMI	IMZ	CD
		n = 91	n=29	n=33	n=29
Are you satisfied or dissatisfied with .					
1.- your dentures in general?	1[a]	21	89	93	71
	2	24	11	7	21
	3	54	0	0	7
2 - your upper denture?	1	63	89	62	89
	2	24	4	35	11
	3	12	7	3	0
3. - your lower denture?	1	1	96	97	32
	2	8	4	3	32
	3	91	0	0	36
4. - the retention of your upper denture?	1	62	81	66	75
	2	23	15	24	14
	3	14	4	10	11
5. - the retention of your lower denture?	1	1	93	100	21
	2	7	7	0	39
	3	92	0	0	39
6. - speech?	1	44	96	93	64
	2	20	4	7	25
	3	36	0	0	11
7. - appearance dentures?	1	53	96	97	89
	2	32	0	3	7
	3	14	4	0	4
8 Is your upper denture causing pain?	1[b]	10	0	7	4
	2	53	11	14	36
	3	37	89	79	61
9. Is your lower denture causing pain?	1	80	0	0	43
	2	19	22	45	50
	3	1	78	55	7

[a] questions 1 - 7: 1 = satisfied 2 = neutral, 3 = dissatisfied
[b] questions 8 and 9: 1 = often , 2 = seldom, 3 = never

Table 5 6 Mean score and sd of the general satisfaction rate, denture complaints questionnaire and chewing ability one year after insertion of the new dentures

	TMI mean (sd) n=29	IMZ mean (sd) n=33	Signifi-cance[1]	95% C.I.[2] TMI-IMZ	CD mean (sd) n=29
General satisfaction[3]					
Satisfaction rate	8 4 (1 3)	8 2 (1 1)	N S	0 41 0 81	6 7 (1 5)
Denture complaints[4]					
Functional complaints mandibular denture	0 27 (0 58)	0 23 (0 26)	N S	0 18 - 0 26	1 22 (0 81)
Functional complaints maxillary denture	0 27 (0 47)	0 96 (0 71)	N S	0 27 - 0 15	0 37 (0 34)
Functional complaints in general	0 20 (0 33)	0 19 (0 20)	N S	0 13 - 0 15	0 69 (0 60)
Physiognomy	0 64 (0 82)	0 37 (0 55)	N S	0 08 - 0 62	0 68 (0 88)
'Neutral space'	0 10 (0 25)	0 24 (0 38)	N S	0 31 - 0 03	0 40 (0 52)
Chewing ability[5]					
Tough food	0 25 (0 58)	0 19 (0 38)	N S	0 19 - 0 31	0 75 (0 68)
Hard food	0 53 (0 71)	0 73 (0 65)	N S	0 55 - 0 15	1 48 (0 63)

[1] Student's t-test, [2] 95% Confidence Intervals, [3] range 0 - 10, [4] range 0 - 3, [5] range 0 2

DISCUSSION

The experiences with surgical procedure were significantly more positive for the TMI-group than the IMZ group 90% of the TMI-group and 64% of the IMZ-group thought the surgery was better than expected 79% of the IMZ-group and only 31% of the TMI-group used analgesics We had not expected this result as an operation under general anaesthesia is thought to be a major operation in comparison with one under local anaesthesia Since the IMZ implants were inserted under local anaesthesia we had expected the results to be the other way around On the other hand patients who knew they were going to have surgery under general anaesthesia were possibly expecting more pain and discomfort than patients who would have surgery under local anaesthesia

Patient satisfaction of mandibular overdentures on dental implants compared to complete dentures was described by Boerrigter *et al* (1995) for the multicenter part of this study Almost all patients with an implant-retained mandibular overdenture were satisfied and compared to patients who received just a new set of dentures the differences were significant The results of this part of the study show that there were no significant differences for any satisfaction, complaint or chewing ability scale when comparing the TMI group with the IMZ group These results were unexpected as the overdentures retained by the transmandibular implant were to a much larger extent supported by the implant and to a lesser degree by the mucoperiosteum of the edentulous mandibular ridge in comparison with the overdentures supported by 2 permucosal implants We had thought the sensitivity of the mucoperiosteum covering the edentulous mandibular ridge of these 'dental cripples' (Atwood, 1971) to be of more influence with respect to patient satisfaction

The results with respect to chewing ability were confirmed by chewing efficiency experiments (Geertman *et al*, 1994) The chewing efficiency of the patients with implant-retained mandibular overdentures was significantly better compared to the chewing efficiency of the patients with new conventional dentures, and the TMI-group did not differ significantly from the IMZ-group

The results of the present study suggest that the retention and stability of the mandibular denture rather than the degree of support by implants determines patient satisfaction However, the sensitivity of the mucoperiosteum covering the

edentulous maxillary ridge, as well as the degree of instability of the maxillary denture may limit the improvement in denture satisfaction

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COMMINUTION OF FOOD WITH IMPLANT-RETAINED MANDIBULAR OVERDENTURES.

Chewing with implant-retained overdentures

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ABSTRACT

When complete denture wearers are treated with from four to six implants and mandibular implant-borne prostheses, masticatory performance improves No significant improvement has been observed with two implants and implant-mucosa-borne overdentures, suggesting that the masticatory performance of edentulous subjects depends on the degree of support for their mandibular prostheses by implants or alveolar mucosa To verify this hypothesis, we studied, in a randomized clinical trial, the comminution of an artificial test food during mastication The trial involved the provision of a new maxillary denture and either a new conventional mandibular denture, a mandibular overdenture retained by two permucosal cylindric implants through a single bar-clip attachment, or a mandibular overdenture retained by a transmandibular implant through five clips on a triple bar construction with cantilever extensions In comparison with the subjects wearing mandibular implant-retained overdentures, the subjects with conventional complete dentures needed between 1 5 and 3 6 times more chewing strokes to achieve an equivalent reduction in particle size No differences in masticatory performance and efficiency were found between the subjects who had received two permucosal cylindric implants and those who had received a transmandibular implant The results suggest that the increased retention and stability of the mandibular denture rather than the degree of support by implants or alveolar mucosa determine the ability to comminute food during mastication

INTRODUCTION

Although many edentulous subjects are quite satisfied with their complete dentures, from 5 to 20% of them are not (Van Waas, 1990) They experience a variety of problems, such as instability of their dentures, oral pain, inability to chew hard or tough foods or food getting under their dentures during chewing (Bergman and Carlsson, 1972, Hartsook, 1974, Brunner and Aeschbacher, 1981) Their ability to comminute foods during mastication is markedly reduced to one-fourth or one-seventh of that of adults with natural dentitions depending on the ages of the subjects and the type of food (Kapur and Soman, 1964, Heath, 1982, Slagter *et al*, 1992a, 1993a) Low correlations have been found

between objective tests of masticatory performance and patients' own assessments of their ability to chew foods, their oral conditions, and the quality of their dentures (Slagter *et al*, 1992b). New conventional complete dentures of optimum quality do not improve masticatory performance predictably (Gunne *et al*, 1982; Gunne and Wall, 1985; Lindquist *et al*, 1986).

Although patients with varying numbers of missing teeth may benefit from dental implants in terms of their masticatory performance (Haraldson and Carlsson, 1979; Lundqvist and Haraldson, 1992), conflicting results have been reported regarding the effects of such treatment in edentulous patients. Lindquist and Carlsson (1985) found that the masticatory performance improved significantly after the insertion of from four to six implants in the lower jaw and the provision of fixed mandibular prostheses. Haraldson *et al* (1988), however, observed no significant change in masticatory performance after the provision of mandibular overdentures retained by two implants. The evidence from these two studies suggests that the improvement in masticatory performance depends upon the degree of support of mandibular prostheses by implants instead of alveolar mucosa. However, a comparison of these studies can be made only with caution. Both studies were restricted to measuring the effects of a single treatment procedure. The studies may have differed in the selection of patients eligible for treatment. Also, the number of participants differed considerably: 27 *vs.* 9. A comparison between groups randomly treated with different methods is needed for further clarification.

To identify the significance of differences in the degree of support of mandibular dentures by implants or alveolar mucosa for the comminution of foods during mastication, we chose a randomized controlled clinical trial (Pocock, 1983) for a comparison between two groups receiving implant treatment and a group of similar patients receiving a standard treatment, *viz.*, the provision of conventional complete dentures. The three groups had the provision of a new maxillary denture in common but differed in the treatment for the mandible: a new mucosa-borne, conventional denture; an implant-mucosa-borne overdenture on two permucosal cylindric implants with a single bar-clip attachment; or a mainly implant-borne overdenture on a transmandibular implant with five clips on a triple-bar construction with cantilever extensions.

MATERIALS AND METHODS

Subjects

Eighty-four edentulous subjects participated (mean age, 57 years, range from 39 to 75) They had been referred to the University of Nijmegen, Clinic of Maxillofacial Prosthodontics and Special Dental Care, by general practitioners because of persistent problems with wearing conventional complete dentures Criteria for inclusion of the subjects in the clinical trial were a mandibular symphyseal bone height of 15 mm or less, as measured on a standardized lateral cephalogram, the absence of medical or psychological risks interfering with the treatment or with implant success, and the agreement of both prosthodontist and oral surgeon on the eligibility for treatment with conventional dentures as well as mandibular implant-retained overdentures Fully informed consent had been obtained from all subjects prior to entry into the trial All of them had been informed that those who were to receive conventional dentures would be eligible for implant treatment if their problems had not been resolved after one year of denture-wearing

Treatment groups

Treatment had been carried out according to routine procedures for the provision of a new maxillary denture and a new mucosa-borne, conventional mandibular denture, or for an implant-mucosa-borne mandibular overdenture retained by two permucosal cylindric IMZ implants (Kirsch and Mentag, 1986) through a single bar-clip attachment, or a mainly implant-borne mandibular overdenture retained by a transmandibular implant (Bosker, 1986) through five clips on a triple-bar construction with cantilever extensions Porcelain teeth were used (Optiform®, ENTA-Lactona, Bergen op Zoom, The Netherlands), designed and arranged according to the lingualized occlusion concept (Becker *et al*, 1977, Lang and Razzoog, 1992)

Allocation of treatment

The subjects had been assigned to one of the three treatment groups according to a balanced method of allocation (Zielhuis *et al*, 1990) to enhance the comparability of the groups with respect to age, gender, years of being edentulous, number of previously made complete dentures, the number of years

of having worn a conventional mandibular denture, and mandibular symphyseal bone height measured on a standardized lateral cephalogram. Descriptive statistics of these variables for the three groups are listed in table 6.1. This procedure had been carried out by an independent person who was not involved in the treatment of any of the subjects.

Table 6.1 Descriptive statistics of the subjects grouped according to treatment

Experimental variable[a]	**CD**	**IMZ**	**TMI**
Number of participants	28	29	27
- male	7	6	7
- female	21	23	20
Years of age	57.7 (9.1)[b]	56.0 (7.6)	56.2 (9.2)
Years edentulous	27.0 (8.9)	23.7 (7.6)	24.1 (7.3)
Number of previous dentures	3.4 (1.3)	3.1 (1.4)	3.5 (1.6)
Years of having worn the last denture	6.3 (4.5)	6.6 (5.4)	5.5 (4.4)
Mandibular symphyseal bone height	13.6 (1.7)	13.9 (1.4)	13.7 (1.7)

[a] CD = conventional mandibular denture, IMZ = mandibular overdenture on two IMZ-implants, TMI = mandibular overdenture on transmandibular implant

[b] mean value (SD)

Experimental procedure

The comminution of a standardized artificial test food (Optocal) based upon the silicone compound Optosil NF® (Bayer AG, Leverkusen, Germany, version 1987) was determined one year after treatment in a series of chewing tests. Force-deformation properties of Optocal have been compared with those of natural foods used for measurements of masticatory performance (Slagter *et al*, 1992c) and have been found to be suitable for measurements of masticatory performance in complete-denture wearers (Slagter *et al*, 1993a). The methods of sieving and analyses described by Slagter *et al* (1992a, 1993a) were used to quantify the particle size reduction during mastication.

All subjects were offered cubes of Optocal with an edge size of 5 6 mm in portions of 17 particles (approximately 3 cm^3) The test food was collected after 10, 20, 40 and 60 chewing strokes The median particle size (X_{50}) was determined for each particle size distribution obtained after completion of a specific number of chewing strokes (N) The number of chewing strokes ($N_{½}$) necessary to reduce the value of X_{50} to half the initial particle size (2 8 mm) was calculated mathematically from the relationship between X_{50} and N (Slagter *et al*, 1993a)

The relationship between the numbers of chewing strokes needed by the conventional denture wearers (N_1) and the wearers of mandibular implant-retained overdentures (N_2) to achieve equivalent reductions in X_{50} was further described by so-called equidimensional curves (Slagter *et al*, 1993a)

Statistics

Differences among the three groups in X_{50} after 10, 20, 40 and 60 chewing strokes, as well as in $N_{½}$, were tested by means of the Mann-Whitney *U* test, with a probability level of 0 05 Bonferroni correction of the probability level was applied for multiple comparisons

RESULTS

Median particle size

Figures 6 1a, b and c give the cumulative relative frequency distributions of the median particle size values in the three groups, after 10, 20, 40 and 60 chewing strokes Since all subjects started with equally sized particles, a certain number of chewing strokes is required before the particle size distributions of the chewed food reflect differences in food comminution during mastication in terms of median particle size (X_{50}) After 10 chewing strokes, the particle size distributions in the three groups were still dominated by large proportions of slightly damaged, partially broken (cracked), or intact particles Hence, no differences in X_{50} were found among the groups after 10 chewing strokes Beyond 10 chewing strokes, a continued presence of slightly damaged, partially broken (cracked) or intact particles was observed in the particle size distributions of the conventional-denture group After 20 chewing strokes, the values of X_{50} reflected an enhanced comminution of the test food by both implant-retained

mandibular overdenture groups compared with the conventional-denture group. Regardless of the number of strokes, no significant differences in X_{50} emerged between both implant-retained overdenture groups throughout the chewing sequence (M-W U test; $0.53 \leq p \leq 0.89$). Therefore, these subjects were taken as one group in subsequent statistical tests. After 20, 40 and 60 chewing strokes, the combined group with implant-retained overdentures showed significantly smaller values of X_{50} than the conventional-denture group (M-W U test; $0.0002 \leq p \leq 0.004$).

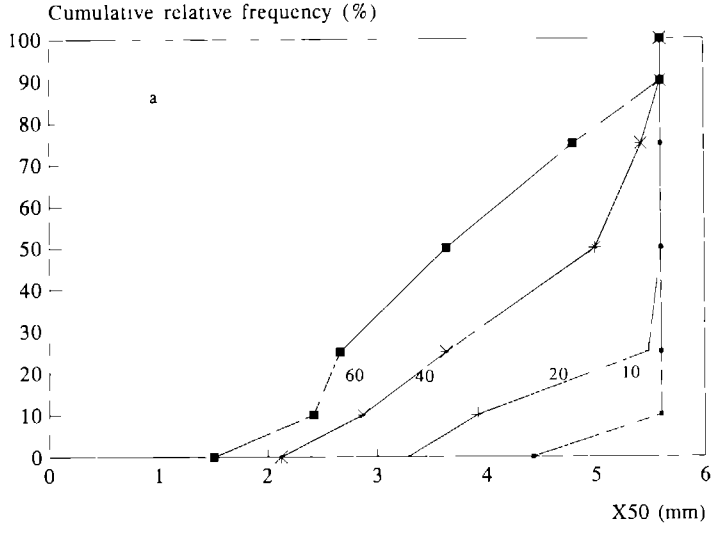

Figure 6.1a Cumulative relative frequency distribution (%) of the values of the median particle size (X_{50}) in the group of subjects wearing conventional mandibular dentures, after 10, 20, 40, and 60 chewing strokes. The data points refer to the following percentiles: 0, 10, 25, 50, 75, 90 and 100

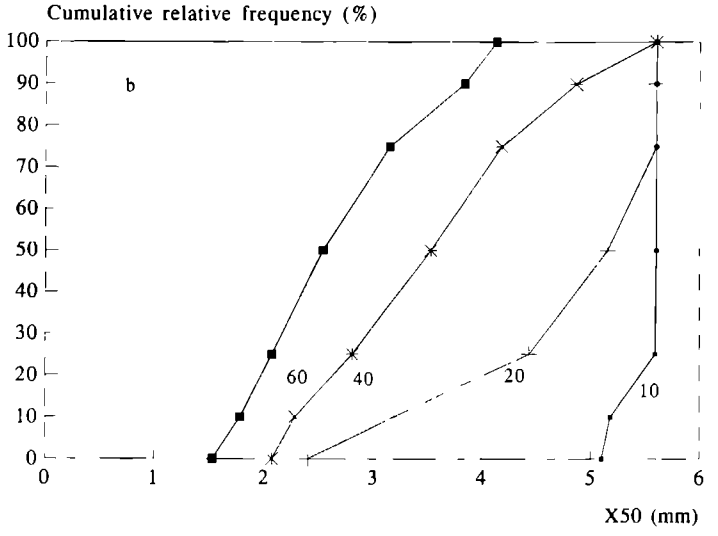

Figure 6.1b Corresponding results for the subjects wearing mandibular overdentures retained by two permucosal implants

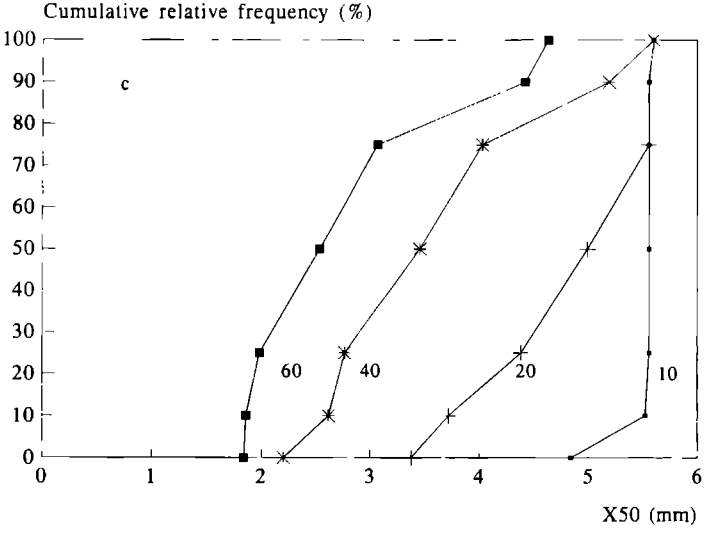

Figure 6.1c Corresponding results for the wearers of mandibular overdentures retained by a transmandibular implant

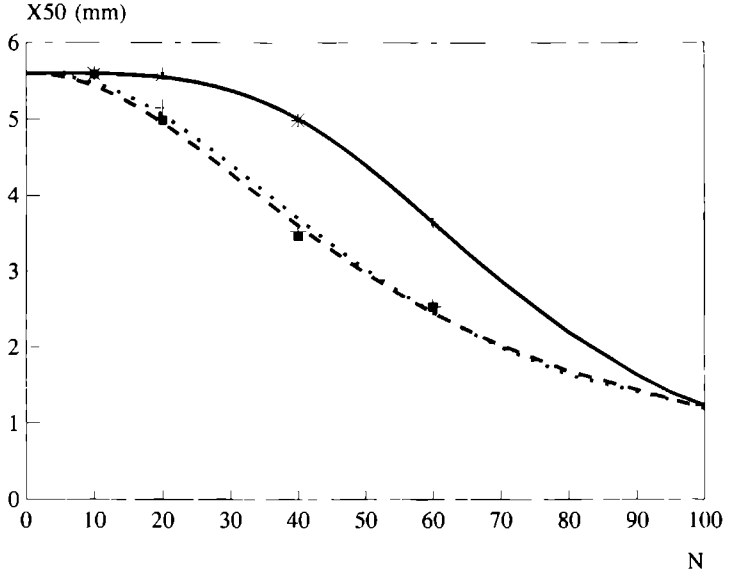

Figure 6.2 The median particle size (X_{50}) plotted as a function of the number of chewing strokes (N) for the conventional-denture wearers (solid curve) and the wearers of mandibular implant-retained overdentures on either two permucosal implants (dotted curve) or a transmandibular implant (dashed curve). Data points indicate the median values of X_{50} for the three groups (*, + and □, respectively)

Reduction in median particle size

Figure 6.2 shows the dependence of X_{50} on the number of chewing strokes for the three groups of subjects. The curves represent best-fits through the data points, based on the median values of X_{50} in each group. Six subjects in the conventional-denture group failed to accomplish any measurable reduction in median particle size, resulting in a theoretically infinite number of chewing strokes to reduce X_{50} to a value of 2.8 mm ($N_{1/1}$). Individual estimates of $N_{1/}$ could not be obtained for these subjects. Three achieved such a limited reduction in median particle size, that $N_{1/}$ reached far beyond 100 chewing strokes. In contrast, all subjects who had been treated with either two permucosal cylindric

implants or a transmandibular implant achieved at least some reduction in median particle size. For two participants with permucosal implants and two with a transmandibular implant, 100 chewing strokes would still be insufficient to halve the initial particle size. Table 6.2 gives the percentile distribution of individual estimates of $N_{1/2}$ in each group. In accordance with the before-mentioned results, the differences in $N_{1/2}$ between subjects with conventional dentures and those with implant-retained mandibular overdentures were highly significant (M-W *U* test; p = 0.0004). Again, the subjects with two permucosal implants did not differ significantly from those with a transmandibular implant (M-W *U* test; p = 0 81).

Table 6.2 The percentile distribution of the number of chewing strokes necessary to halve the initial particle size

Experimental variable[a]	**CD**	**IMZ**	**TMI**
Percentiles			
100	∞	105	200
90	∞	86	99
75	193	63	61
50	68	52	51
25	56	43	41
10	47	35	36
0	27	25	34

[a] CD = conventional mandibular denture, IMZ = mandibular overdenture on two IMZ-implants, TMI = mandibular overdenture on transmandibular implant

Equidimensional curves

Figure 6.3 shows the equidimensional curves for comparison of the comminution of Optocal by the two groups wearing implant-retained mandibular overdentures with that by the conventional-denture wearers throughout the chewing sequence. The more the curves deviate from the line $N_1 = N_2$, the larger the differences between the two processes of food comminution that are being compared. The ratio of the number of chewing strokes needed by the conventional-denture group

and that needed by the wearers of mandibular implant-retained overdentures to reach equivalent reductions in X_{50} ranged from 3.6 after 20 chewing strokes to 1.5 after 60 chewing strokes. In an extrapolation of the results beyond 60 chewing strokes, the differences in chewing efficiency between the groups tended to fade. Theoretical values of about 100 chewing strokes would be required for the median values of X_{50} in the three groups to converge.

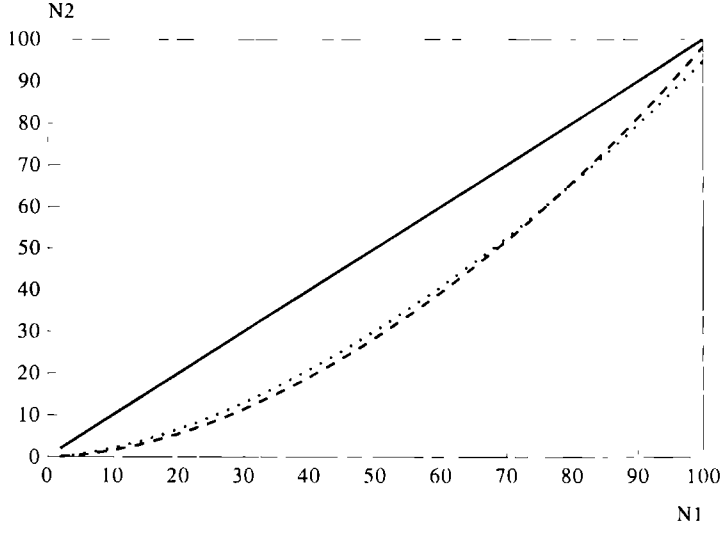

Figure 6.3 The equidimensional curves, representing the relationships between the numbers of chewing strokes needed by the conventional-denture wearers (N_1) and those needed by the wearers of mandibular overdentures (N_2) on either 2 permucosal implants (dotted curve) or a transmandibular implant (dashed curve) to reach the same reduction in median particle size (X_{50}). Solid line: $N_1 = N_2$

DISCUSSION

The chewing experiments were carried out among participants in a randomized controlled clinical trial. Similar groups of patients were obtained by means of a balanced method of treatment allocation. Some overlap existed between individual wearers of conventional dentures and subjects wearing mandibular implant-retained overdentures regarding the degree of food comminution they achieved (Figs 1a, b and c). One individual conventional-denture wearer even outweighed the subjects wearing mandibular implant-retained overdentures regarding the reduction in median particle size, indicating that all edentulous subjects with severely resorbed mandibles do not necessarily have a poor masticatory performance and chewing efficiency after treatment with conventional dentures. Nevertheless, the overall results show that one year after treatment the chewing efficiency of patients with persistent problems wearing complete dentures was substantially better with implant-retained mandibular overdentures than with new conventional dentures. These findings are in contrast to the non-significant improvement in masticatory performance reported by Haraldson *et al* (1988) after the provision of mandibular overdentures supported by two permucosal cylindric implants.

For the present study no chewing experiments had been carried out before treatment, so intra-individual changes in masticatory performance and efficiency as a result of treatment are unknown. The intra-individual changes in masticatory performance measured by Haraldson *et al* (1988) can be ascribed to cumulative effects of both the transition from old to new dentures and the enhanced retention, stability and support for the mandibular overdenture by implants. In the present study considerable variation existed among the subjects in the quality of their dentures prior to entry into the clinical trial. The transition from old to new dentures may affect masticatory performance in a positive as well as a negative way (Gunne *et al*, 1982; Gunne and Wall, 1985; Lundquist *et al*, 1986). The present clinical trial involved an interindividual comparison between independent, but highly comparable groups of patients who had all received new maxillary as well as mandibular (over)dentures during the course of treatment. This rules out the possibility that the differences in masticatory performance and efficiency observed between the subjects with mandibular conventional dentures and those with implant-retained overdentures can be

accounted for by the transition from old to new dentures, with the concurrent improvement in denture quality

Several limitations of the method used by Haralson *et al* (1988) for determining masticatory performance may further explain why these authors failed to observe any significant improvement in masticatory performance after treatment with implant-retained mandibular overdentures The method according to Helkimo *et al* (1978) is based upon the comminution of a natural test food (almonds) The variation in shape, size and physical properties of almond particles contributes to experimental scatter The use of only three sieves to separate the particles in the chewed food according to their size is insufficient for accurate determination of the most representative measure of distribution location the median particle size by cumulative weight or volume (Van der Bilt *et al*, 1993) The use of an arbitrary, qualitative index based upon the number of particles on each sieve for classification of the result of the chewing process precludes detailed analyses of the reduction in particle size This index depends upon the apertures of the sieves chosen, applies to almonds only and is not generally applicable to other comminutable test foods The present study used a standardized artificial test food, a multi-sieve system and a more rigorous method of analyzing the reduction in particle size during mastication

Slagter *et al* (1993a,b) found the mean values of $N_{1/}$ for Optocal to differ between 15 in a group of seven dentate subjects, aged between 50 and 71 years, and 44 in a group of six conventional-denture wearers, aged between 33 and 70 All denture wearers in these studies were able to comminute Optocal, and their subjective judgment of the test food texture was that is was rather easy to chew The denture wearers in both studies had no complaints They were satisfied with their dentures and did not require treatment Their dentures had not been made according to the concept of lingualized occlusion Furthermore, the number of denture wearers was limited Therefore, a comparison with the results of the present study is difficult The median values of $N_{1/}$ in the present study as well as the finding that six subjects failed to accomplish any measurable reduction in particle size suggest that the conventional-denture group had a very poor masticatory performance and chewing efficiency compared with the values reported for denture wearers (Slagter *et al*, 1993a,b) Since the participants in the present study had persistent problems with wearing their dentures and were known to have compromised oral conditions, this is no surprise, but it is worse

than expected, given that "normal" denture wearers found Optocal rather easy to chew (Slagter *et al*, 1993a)

The values of $N_{/}$ for both implant-retained overdenture groups overlap with those of the conventional-denture wearers in the studies by Slagter *et al* (1993a,b) As far as a comparison can be made between these studies and the present one, it seems that the provision of implant-retained overdentures to denture wearers with persistent problems wearing conventional dentures and with compromised oral conditions restores their ability to comminute food during mastication to the levels achieved by satisfied conventional-denture wearers

The overdentures retained by a transmandibular implant were to a much larger extent supported by this implant and to a lesser degree by the mucoperiosteum of the edentulous mandibular ridge than were the overdentures retained by two permucosal cylindric implants In view of this difference, the similarity in chewing efficiency of both groups wearing implant-retained overdentures was unexpected In several studies on masticatory performance and bite force, the sensitivity of the mucoperiosteum covering the edentulous mandibular ridge has been hypothesized as a factor limiting these oral functions (O'Rourke, 1949, Wennstrom, 1971, Kapur and Garrett, 1984, Hardtmann *et al*, 1989, Slagter *et al*, 1993b) The results of the present study suggest that the retention and stability of the mandibular denture, rather than the degree of support by implants or mucosa determine an individual's ability to comminute foods during mastication At the same time, however, the sensitivity of the mucoperiosteum covering the edentulous maxillary ridge, as well as the degree of instability of the maxillary denture may limit the improvement in chewing efficiency Further research regarding the chewing efficiency of edentulous subjects treated successively with implants in the mandibular as well as in the maxillary jaw may clarify these hypotheses

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CHAPTER 7

MASTICATORY PERFORMANCE AND CHEWING EXPERIENCE WITH IMPLANT-RETAINED MANDIBULAR OVERDENTURES

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ABSTRACT

The relationship between masticatory performance and chewing experience has not yet been explored for patients with implant-retained overdentures Although many relationships have been found between parameters of objective and subjective oral function, the structure of these relationships remain unclear Therefore, we studied in a randomized clinical trial the relationship between the comminution of an artificial test food, i e masticatory performance, and the subjective chewing experience The trial involved a comparison between two groups receiving implant treatment and one group receiving conventional complete dentures (CD) The implant treatment involved either a mainly implant-supported mandibular overdenture on a transmandibular implant (TMI) or an implant-tissue supported mandibular overdenture on two IMZ implants (IMZ) Masticatory performance as well as chewing experience were substantially better for the implant-retained overdentures compared with the complete denture group No significant differences emerged between the TMI- and the IMZ-group A multiple regression analysis did not provide any comprehensibility in the relationship between masticatory performance and the variables of chewing experience In the Linear Structural Relation analysis (LISREL) no direct relationship was found between masticatory performance and functional complaints mandibular denture The results show that an improvement in masticatory performance does not imply the same improvement in chewing experience and vice versa

INTRODUCTION

The masticatory performance, e g the comminution of food, of complete denture wearers is markedly reduced to one-fourth to one-seventh of that of adults with natural dentitions, depending on the age of the subjects and the type of food (Kapur and Soman, 1964, Heath, 1982, Slagter *et al*, 1992a, 1993) 5 to 20% of these subjects are not satisfied with their dentures (Van Waas, 1990) They experience a variety of problems, such as inability to chew tough or hard foods, oral pain or instability of their dentures (Bergman and Carlsson, 1972, Hartsook, 1974, Brunner and Aeschbacher, 1981) Low correlations have been

found between masticatory performance, the patients' own assessment of their ability to chew foods, denture satisfaction, the oral condition and the quality of the dentures (Slagter *et al*, 1992b). New conventional dentures do not enhance the masticatory performance of edentulous subjects in a predictable way (Gunne *et al.*, 1982; Gunne and Wall, 1985; Lindquist *et al*, 1986).

Treatment with fixed mandibular implant-supported prostheses has shown a substantial improvement in masticatory performance as well as subjective chewing experience (Haraldson and Carlsson, 1979; Carlsson and Lindquist, 1994). Feine *et al* (1994a) made intra-individual comparisons between implant-supported fixed mandibular prostheses and long-bar implant-supported over-dentures. From their observations, in terms of masticatory time and masticatory movements, it may be assumed that an implant-supported overdenture is no less efficient than a fixed prosthesis with respect to masticatory function (Feine *et al*, 1994b). However, these authors did not measure the comminution of food during mastication. Haraldson *et al* (1988) observed no significant change in masticatory performance after the provision of a mandibular overdenture retained by two implants, despite an improvement according to the patient's view. The evidence of these studies suggests that the masticatory performance and chewing experience depend on the degree of implant-support of mandibular overdentures. Since it is difficult to make a comparison between these studies, a well-controlled randomized clinical trial is needed for further clarification. For this reason, a study of this design was carried out with two types of mandibular overdentures differing in implant support versus conventional mandibular dentures.

Subjective experience and masticatory performance with complete dentures are multi-factorially determined. (Slagter *et al*, 1992b, Van Waas, 1990). A considerable number of variables may play a role, such as age, gender, number of years being edentulous, oral conditions, denture mobility and the subjective experience wearing dentures. Although many relationships have been found between parameters of objective and subjective oral function, the structure of these relationships remains unclear. The provision of implants to edentulous subjects in the above-mentioned trial can be regarded as an 'experimental variable' influencing oral function with complete dentures at several levels. This paper describes a model for the structure of the relationships between objective

and subjective parameters of oral function in an overall analysis, aiming at more insight into their relative meaning. Such knowledge may improve clinical decision-making as regards the eligibility of edentulous patients for implant treatment.

MATERIAL AND METHODS

Study design and patient selection

The randomized clinical trial involved a comparison between two groups receiving implant treatment and one group receiving a standard treatment with conventional complete dentures (CD). The implant treatment involved either a mainly implant-supported mandibular overdenture on a transmandibular implant (TMI) or an implant-tissue supported mandibular overdenture on two IMZ implants (IMZ). In the maxilla all patients received a conventional complete denture.

Treatment was allocated to 95 patients with severely resorbed mandibles and persistent problems wearing conventional complete dentures, using a balancing procedure (Zielhuis *et al*, 1990). Six patients refused the allocated treatment, four were lost to follow-up and one TMI was removed. One year after insertion of the new dentures the group consisted of 84 patients: 64 females and 20 males, their age varied from 39 to 75 years, with an average of 57. They had been edentulous for an average of 24 years. Written informed consent had been obtained from all participants prior to entry into the trial. The study design has been described previously (Geertman *et al*, 1994, 1995).

Treatment groups

With respect to the mandibular denture three different treatment modalities were applied: one group received a mainly implant supported overdenture retained by a transmandibular implant through five clips and a triple bar construction with cantilever extensions (Bosker 1986). The second group received an implant-tissue supported overdenture retained by two permucosal cylindric IMZ implants through a single bar-clip attachment (Kirsch and Mentag, 1986). The third group was treated with a new mucosa supported conventional mandibular denture. All patients received a new maxillary denture.

Masticatory performance tests

The comminution of a standardized artificial test food (Optocal, Slagter *et al*, 1993) based upon the silicone compound Optosil NF[IM] (Bayer, Leverkusen, Germany, version 1987) was determined one year after insertion of the new prosthesis All patients were offered 17 cubes of Optocal with an edge size of 5 6 mm (approximately 3 cm^3) The test food was collected after 60 chewing strokes The median particle size (X_{50}, Olthoff *et al*, 1984) was determined from the particle size distribution, and is further described (after mirroring) as masticatory performance

Immediately after the chewing test the patients were interviewed according to a questionnaire regarding difficulty in chewing Optocal, pain and loss of retention of the maxillary as well as the mandibular denture A scale ('chewing test experience') was constructed of all questions and the reliability was determined by Cronbach's α It appeared to be satisfactory, Cronbach's α = 0 79

Chewing experiences

One year after insertion of the new dentures patients' opinions about their (over)denture were assessed using the following variables

- Denture complaints, assessed by a 54-item questionnaire (Vervoorn *et al*, 1988) Each item could be answered on a 4 point rating scale (0=no complaints, 3=severe complaints) Factor analyses were carried out, producing six factors functional complaints mandibular denture (e g 'lower denture gets loose during speaking'), functional complaints maxillary denture (e g 'upper denture gets loose during eating'), functional complaints in general (e g 'full sensation due to the denture'), physiognomy (e g 'mouth has fallen-in'), neutral space (e g 'lip or cheek biting'), aesthetics (e g 'teeth are too big') The reliability of these factors was expressed by Cronbach's α Values of α appeared to be satisfactory, ranging from 0 76 to 0 90
- Chewing ability, assessed by questions about eight different types of food The items could be answered on a 3 point rating scale (0=good, 2=bad) Again, factor- and reliability analyses were carried out, producing three factors 'soft food' (e g vegetables), 'tough food' (e g steak, cheese), 'hard food' (e g apple, carrot) Cronbach's α ranged from 0 74 to 0 81 It appeared that the

factors 'tough' and 'hard' food were correlated (r=0 73) and could be taken together (Cronbach's α = 0 84)
- Overall denture satisfaction, expressed on a 10-point scale (1-10)

Statistical analysis
Pearson's coefficients of correlation were calculated to determine the existence and strength of any association between the masticatory performance and the following variables gender, age, edentulous period of the mandible, mandibular symphyseal bone height, 'implants present' (yes or no), the scales 'functional complaints mandibular denture ' and 'functional complaints maxillary denture ' of the complaint questionnaire, the scale 'tough/hard food' of the chewing ability questionnaire, 'chewing Optocal' and the overall denture satisfaction rate Multiple regression analyses with stepwise forward variable selection were carried out to explain the masticatory performance

While multiple regression analyses can be used to determine the variation in masticatory performance and functional complaints explained by related variables, these analyses do not provide any structural framework for their hierarchy and interdependence A more sophisticated approach was found in the Linear Structural Relation analysis (LISREL, Joreskog and Sorbom, 1989, Verschuren 1991) It offers a possibility to test and verify an assumptive, preliminary model (comprising all parameters) as a whole and thus put the measurements within a logical framework

Based on the present knowledge an initial model was constructed (fig 7 1) Patient satisfaction can be considered as the ultimate goal of treatment and is placed at the rear end of the model Gender and the provision of implants can be considered as independent variables, therefore these are placed up front as exogenous variables Chewing test experience, i e the mobility of the denture and pain during chewing rather determine the masticatory performance than depend on it The purpose of this Lisrel application is to test a direct influence of masticatory performance on 'functional complaints mandibular denture' and 'overall satisfaction rate' (see question marks) versus an indirect influence (e g via treatment)

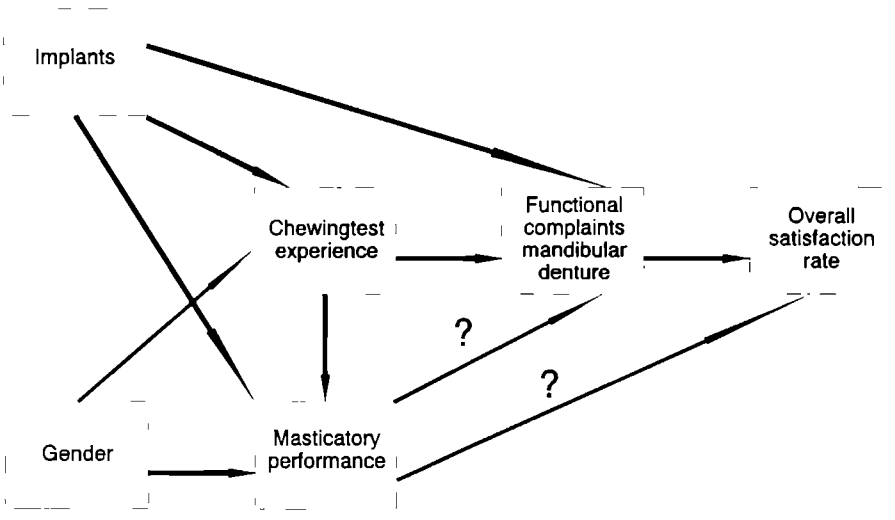

Figure 7.1 The initial model

RESULTS

Masticatory performance tests

The masticatory performance of patients with implant-retained mandibular overdentures after 60 chewing strokes was substantially better than with new conventional complete dentures (Geertman *et al*, 1994). No significant differences in masticatory performance emerged between the TMI- and IMZ-group.

Table 7.1 shows the distribution of answers to the questions concerning the chewing test. Both implant groups answered not to have much trouble chewing the test food. The CD-group answered to have more problems: more than half of the patients complained about mobility of the mandibular denture during chewing. Both implant groups had more problems than the CD-group as regards the mobility of the maxillary denture during chewing.

Table 7.1 Answers to the questions concerning the chewing test (in percentages)

		TMI	IMZ	CD
(1) Did you have difficulties chewing the test food?	1*	0	4	7
	2	8	14	29
	3	92	82	64
(2) Was the lower jaw hurting during chewing?	yes	4	4	21
	no	96	96	79
(3) Did the upper denture come loose during chewing?	yes	20	14	4
	no	80	86	96
(4) Did the lower denture come loose during chewing?	yes	0	4	54
	no	100	96	46

* 1 = (very) much, 2 = somewhat, 3 = (very) few

Chewing experience

The implant-groups showed less complaints compared with the CD-group on the scales 'functional complaints mandibular denture', 'functional complaints in general ' and 'neutral space ' The differences between the TMI- and IMZ-group were not significant No differences between the groups were found on the other scales A similar treatment outcome was found in terms of chewing ability both implant groups showed better scores on the factors 'tough' and 'hard' food than the CD-group, no differences were found between both implant groups Overall satisfaction (10-pt scale) was high for both implant groups, with mean values of 8 4 and 8 2 for the TMI- and IMZ-groups Again the values for the CD-group were significantly less favourable with a mean score of 6 7 These results have been described in detail in a previous paper (Geertman *et al,* 1995)

Multiple regression analyses

The variable 'implants present' accounted for 19% of the variance in masticatory performance As this item by itself does not provide insight into the relationship between functional complaints, chewing experience of masticatory performance and overall satisfaction, it was left out of the multiple regression analysis

The relationship between the masticatory performance and the independent variables, expressed in Pearson's correlation coefficient, is shown in the first column of table 7 2 Masticatory performance did not significantly correlate with age, symphyseal bone height and the scale 'functional complaints maxillary denture' The variables with a relatively high correlation with masticatory performance were 'functional complaints mandibular denture' (r=-0 48) and 'chewing test experience' (r=-0 43)

The multiple regression analysis (with all variables of table 7 2) selected the following variables (1) 'functional complaints mandibular denture' and (2) gender The second and third column of table 7 2 show the correlations partialled out for these variables in order of selection A comparison between the first and second column shows that the relationships between masticatory performance and several of the independent variables lost much of their strength after entering 'functional complaints mandibular denture' into the equation The relationship between 'functional complaints mandibular denture' and the other variables expressed in simple correlation coefficients is shown in the last column of table 7 2 The relationships between 'complaints mandibular denture' and the variables concerning the subjective evaluation were stronger than those between the masticatory performance and the latter

The independent variables 'functional complaints mandibular denture' and gender accounted for 30% of the variance in masticatory performance

Table 7.2 Correlation between masticatory performance and independent variables, using correlation coefficient (*r*); correlations partialled out for the selected variable; correlation between 'functional complaints mandibular denture' and the independent variables

		Multiple regression analysis		
	simple *r*	**Coefficients partialled out for the selected variable**		**simple** *r*
	masticatory performance	**complaints mandibular denture**	**gender**	**complaints mandibular denture**
Gender (♂ → ♀)	-0.31**	-0.33**	xx	-0.03
Age	-0.18	-0.08	-0.19	-0.24*
Symphyseal bone height	0.03	0.05	0.05	-0.03
Edentulous period mandible	-0.26*	-0.19	-0.23*	-0.21
Overall satisfaction rate	0.32**	-0.03	0.02	0.69**
'Chewing tough/hard food'	-0.29*	0.11	0.10	-0.74**
'Functional complaints mandibular denture'	-0.48**	xx	xx	xx
'Functional complaints maxillary denture'	-0.03	0.19	0.22	-0.38**
'Chewing test experience'	-0.43**	-0.16	-0.11	-0.68**
Adjusted R^2		0.22	0.30	

* significance level , $0.01 < p < 0.05$
** significance level , $p < 0.01$

LISREL-analyses

The initial model (fig. 7.1) was verified using the LISREL technique. The unknown relationships, as expressed by the LISREL-coefficients, were tested by t-values (estimated coefficients). The unknown t-values were not significant and

this model was rejected Modifications to the model were made, based on an inspection of the analysis of the initial model and the final model was constructed (fig 7 2) This model fitted well $\chi^2_6 = 7\ 14$ ($p = 0\ 31$), the goodness of fit index was 0 97 and the adjusted goodness of fit index 0 91

The path-coefficients of all the indicators in this model were significant A relationship was found between 'implants' and 'functional complaints mandibular denture', 'implants' and 'chewing test experience', 'implants' and masticatory performance' and gender and masticatory performance A weak relationship was found between 'chewing test experience' and masticatory performance The relationship between gender and chewing test experiences was only just significant No direct relationship was found between masticatory performance and 'functional complaints mandibular denture'

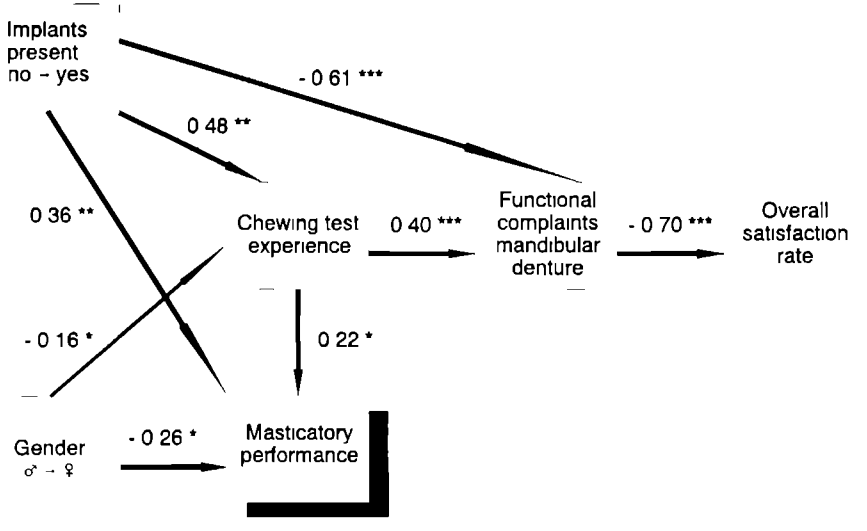

Figure 7.2 The final LISREL model

DISCUSSION

In this study the findings of masticatory performance as well as chewing experience were substantially better for the implant-retained overdentures compared with the CD-group Contrary to expectations based on the existing literature (Haraldson and Carlsson, 1979, Haraldson *et al*, 1988, Carlsson and Lindquist, 1994, Feine *et al*, 1994a,b, de Grandmont *et al*,1994), differences between the TMI- and IMZ-group were not significant The relationship between masticatory performance and chewing experience has not yet been explored for patients with implant-retained overdentures

As expected both implant groups reported less problems during the chewing test than the CD-group (table 7 1) Although mobility of the maxillary denture was experienced more often in the implant groups, this was not apparent in terms of denture complaints or overall denture satisfaction Furthermore, 'functional complaints maxillary denture' did not influence the masticatory performance (r=0 03) Although It has been assumed that implant treatment in the mandible may cause problems with the maxillary denture (Naert *et al*, 1988), the above-mentioned results indicate that this potentially negative side-effect is overruled by the positive outcome of implant treatment on other functional aspects of wearing dentures, given that denture complaints were less with implants and overall satisfaction was high

In terms of Pearson's correlation coefficient significant moderate relationships were found between the masticatory performance and gender, edentulous period mandible, overall satisfaction rate, the chewing ability scale 'tough/hard' food, 'functional complaints mandibular denture', 'functional complaints in general' and 'chewing test experience' The influence of gender is in accordance with other studies showing higher masticatory performance scores and bite force values for men than for women (Lundquist *et al*, 1986, Bakke *et al*, 1990) The influence of the variables of chewing experience was not strong, which is in accordance with other studies masticatory performance correlated weakly with chewing ability in patients with fixed implant-supported mandibular prostheses and maxillary dentures (Lindquist and Carlsson 1985) and even less in patients with fixed maxillary and mandibular prostheses (Carlsson and Lindquist, 1994) The simple regression analysis confirmed the moderate relationship

'functional complaints mandibular denture' was able to explain 22 % of the variance in masticatory performance.

In the final LISREL model no direct relationship between masticatory performance and 'functional complaints mandibular denture' was found, however a weak relationship was found between 'chewing test experience' and masticatory performance.

The provision of dental implants and implant-retained mandibular overdentures resulted in significantly better chewing test experience, masticatory performance, less complaints and higher overall satisfaction compared with conventional complete denture treatment. The LISREL analyses yielded direct relationships between chewing test experience, functional complaints regarding the mandibular denture and overall satisfaction. At the same time, the objective result of chewing in terms of comminution of food, i.e. masticatory performance, was not found to be of direct importance for subjective treatment outcome. Thus, for an individual a certain level of masticatory performance is not predictive for subjective experience in terms of denture complaints and overall satisfaction and vice versa. A parallel can be noticed between these findings and the absence of a correlation between objective and subjective masticatory function, despite significant functional improvements observed in objective as well as subjective measures after prosthodontic replacement of missing post-canine teeth (Van der Bilt *et al*, 1994).

Apparently, to determine eligibility for implant treatment upon assessment of patients, concurrences as well as discrepancies can be encountered between parameters of objective and subjective oral function. When the objective and subjective parameters are in agreement and positive there is obviously no need for further treatment, when both are negative (further) treatment should be considered. Discrepancies in terms of objective and subjective function suggest that patients' demands and expectations are either very modest and easily met or extremely high. When the expectations are extremely high implant treatment may not provide the expected improvement in the subjective function. In this way masticatory performance tests can be relevant for the evaluation of subjective oral function and the assessment of treatment need.

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CHAPTER 8

GENERAL DISCUSSION

The aim of this study was to assess the treatment effects of implant-retained mandibular overdentures, using three different implant systems, compared with new conventional complete dentures. The only study design that enables such a comparison is a phase III randomized clinical trial (Fiorellini and Weber, 1994). For that reason a two-center clinical trial was started in the fall of 1989 at the Universities of Nijmegen and Groningen. In this thesis the treatment effects of patients with severely resorbed mandibles, e.g. a mandibular symphyseal bone height between 8 and 15 mm as measured on a standardized lateral cephalogram, are described. The two-center part (Chapter 2-4) deals with clinical as well as patient related aspects in a comparison between implant-retained mandibular overdentures (IRO) and new complete dentures (CD). The part only performed in Nijmegen (Chapter 5-7), deals with patient related aspects in a comparison between implant-tissue supported overdentures on two IMZ implants and mainly implant-supported overdentures on a TMI, as well as differences between the three treatment modalities in comminution of food using artificial test food, and the relationship between the masticatory performance and chewing experience.

This study meets the requirements of a phase III clinical trial described by Pocock (1983) with the exception of performing it double-blind. Clinical trials should be performed double-blind in order to reduce the bias that can occur if everyone involved in the trial is aware of which treatment each patient is receiving (Pocock, 1983). However, in operative trials it is often not possible to accomplish blindness. In this trial the patient, the treatment team and the evaluators were aware of implants being present or not.

It took two years to select 157 patients who were eligible and willing to enter the trial. The long intake period can be partly explained by the inclusion-criteria (table 2.1). Only patients with severely resorbed mandibles were allowed to enter the study. Furthermore the patients were randomly assigned (by a balancing procedure) to the different treatment groups. This was an uncertain factor for the patients: there was a chance on implant treatment with general or local anaesthesia and on treatment with just a new set of dentures. Therefore several patients refused consent.

At entry into the trial the objectives and the consequences of participating in the trial were carefully explained to all patients to reduce treatment refusal. Nevertheless, 9 of the 157 selected patients refused treatment after

allocation had taken place To prevent selection bias the 'Intention To Treat' principle was applied (Chapter 2) This means that all patients are evaluated in the originally allocated treatment group, regardless the actual treatment they received This principle is only applied in the evaluation of the patient's experiences (Chapters 2,3 and 5) In the clinical evaluation and masticatory performance tests this was of course not possible

The comparison of general characteristics at entry indicates that the balancing procedure indeed provided similar treatment groups No differences were present with respect to patient's experiences with the previous conventional dentures All patients were dissatisfied with their mandibular denture and could hardly chew tough or hard foods (Chapters 2,3 and 5)

Two-center clinical trial

The group with Implant-Retained Overdentures (**IRO**) appeared to be very satisfied and had few complaints (table 3 5 and 3 6) This favourable outcome was also reflected by the overall satisfaction rate the majority of the IRO-group (85%) had a score of 8 or even higher These findings are consistent with those of previous studies (Van Waas and Bosker, 1989, Clancy *et al*, 1992, Wismeijer *et al*, 1992, Harle and Anderson, 1993) The overall results (Chapter 3) are also in accordance with the favourable results achieved with fixed mandibular prostheses on implants (Blomberg and Lindquist, 1983, Hoogstraten and Lamers, 1987, Grogono *et al*, 1989, Kiyak *et al*, 1990, Kent and Johns, 1994)

The results of the Complete Denture group (**CD**, Chapter 3 and 5), treated with a new set of conventional dentures, were less favourable than those of the IRO-group Regarding the main problem area in the CD-group, i e the mandibular denture, one third of the total number of patients was dissatisfied, one third was neutral and only one third was satisfied These results were more negative than in comparable research projects (Engels, 1986, Van Waas *et al*, 1992)

Regarding the maxillary denture the IRO-group did not show better scores than the CD-group It is sometimes assumed that implant treatment in the mandible may cause complaints about the maxillary denture (Naert *et al*, 1988) This supposition was not confirmed by results of this study

The IRO-group scored significantly better than the CD-group with regard to the chewing ability (Chapter 2) These results are in accordance with those of Lindquist and Carlsson (1985) for fixed prostheses The CD-group still had problems chewing tough and hard foods, these findings are consistent with the study of Gunne and Wall (1985) They reported that new conventional complete dentures improved the subjective chewing ability, but chewing tough or hard foods was difficult

With regard to the clinical aspects three different implant systems were compared, i e the Brånemark system (**BRÅ**), the IMZ system (**IMZ**) and the transmandibular implant system (**TMI**) The scores of the Plaque, Gingiva and Bleeding Index were favourable (Chapter 4 2) and seem to be comparable with those of studies on implant-retained overdentures (Quirynen *et al*, 1992, Gotfredsen *et al*, 1993, Batenburg *et al*, 1994, Mericske-Stern *et al*, 1994, Naert *et al*, 1994) The results of the radiographical evaluation showed mainly 'no apparent bone loss' or 'a reduction of the bone level not exceeding 1/3 of the implant length' for all implant systems (table 4 2 4) Differences between the three systems were not significant Chaytor (1993) described that the first year of functioning includes the bone remodelling phase and subsequent years will exhibit a much lower rate of bone loss This is confirmed by other studies (Ahlqvist *et al*, 1990 Naert *et al*, 1991) The results of this study are of the first year of functioning, so some bone level changes are to be expected Moreover, of each implant/post the most unfavourable value was used Results would have been better when the mean scores were presented instead of the most unfavourable value, as averaging masks greater variations in individual measurements

The Clinical Implant Performance scale (CIP-scale) has been developed in order to be able to compare the different implant systems, including all the complications that can occur So far most studies about implant systems reported on survival rates The data of these studies only represent the percentages that have not been removed The success criteria of Smith & Zarb (1989) are much more specified but still have an absolute character of yes or no with respect to success or failure We have constructed a scale that not only includes the success criteria of Smith & Zarb but all the complications, surgical as well as prosthetic, that may occur in order to be able to compare the different implant systems (Chapter 4 1) The differences in the mean scores of the three implant systems

on the CIP-scale were not significant The TMI-group, however, displayed more complications than the other two implant groups (Chapter 4 2) Taken the literature into account significant differences might occur in future (Bosker *et al*, 1991, Sindet Pedersen, 1991) The results regarding implant loss of the IMZ- and BRÅ-group are in accordance with the results of Naert (1991) who compared both implant systems retaining overdentures

The clinical results do not reveal significant differences between the implant systems one year after insertion of the new dentures To assess the differences between the three implant-systems long-term evaluation is necessary

Clinical trial Nijmegen

The results of this part of the study show that there were no significant differences in patient satisfaction, complaints about the dentures or subjective chewing ability when comparing the TMI- with the IMZ-group (Chapter 5) These results were unexpected as the overdentures retained by a transmandibular implant were to a much larger degree implant-supported in comparison with the overdentures supported by 2 permucosal implants We had thought the sensitivity of the mucoperiosteum covering the edentulous mandibular ridge of these 'dental cripples' to be of more influence with respect to patient satisfaction

The results with respect to the subjective evaluation were confirmed by masticatory performance experiments (Chapter 6) The masticatory performance of the patients with implant-retained mandibular overdentures was significantly better compared with the masticatory performance of the patients with new conventional dentures The TMI-group did not differ significantly from the IMZ-group Some overlap existed between individual wearers of conventional dentures and patients wearing mandibular implant-retained overdentures regarding the degree of food comminution they achieved (Figs 6 1a, b and c) One individual conventional-denture wearer even outweighed the patients wearing mandibular implant retained overdentures regarding the masticatory performance The median values of $N_{/}$ in the CD-group as well as the finding that six patients failed to accomplish any measurable reduction in particle size suggest that the conventional-denture group had a very poor masticatory performance and chewing efficiency, compared with the values reported for complete denture wearers (Slagter *et al*, 1993a,b)

The relationship between masticatory performance and chewing experience, i e subjective evaluation, has not yet been explored for implant-retained overdentures In this study this relationship was not strong (Chapter 7) A Linear Structural Relation (LISREL) analysis was performed to describe the structure of relationships between masticatory performance and chewing experience in terms of 'functional complaints mandibular denture', 'overall satisfaction rate' and 'chewing test experience', to provide insight in their relative contribution No direct relationship was found in the final LISREL model between masticatory performance and 'functional complaints mandibular denture' and masticatory performance and the overall satisfaction rate (fig 7 2) A weak relationship was found between 'chewing test experience' and masticatory performance Thus, for an individual a certain level of masticatory performance is not predictive for subjective experience in terms of denture complaints and overall satisfaction and vice versa

The results of this study show that patients with severely resorbed mandibles, with persistent problems wearing conventional complete dentures, benefit from implant overdenture treatment Almost all patients were satisfied, hardly complain about pain or mobility of the mandibular denture and indicate that they are able to chew tough and hard foods The conventional treatment method, however, is not unreal for patients with severely resorbed mandibles since 1/3 was satisfied, 1/3 was dissatisfied and 1/3 is neutral As success is often unpredictable, implant treatment should be considered when conventional denture treatment does not provide a satisfactory result for the patient

As the results of this study are based on a 1-year evaluation, the clinical results should be considered with caution Most complications and failures occur immediately after insertion of the implant(s) and during the first year of functioning However, this does not mean that no complications or failures will occur on the long term, especially since implants were placed in severely resorbed mandibles Long-term results remain to be evaluated to assess the real benefits of implant overdenture therapy

Conclusions

- Patients with implant-retained overdentures compared with conventional complete denture wearers had less complaints, are more satisfied and had a better subjective chewing ability and masticatory performance
- Patients with implant tissue supported overdentures compared with patients with mainly implant-supported overdentures did not differ in patient satisfaction, complaints about the dentures, subjective chewing ability and masticatory performance
- One third of the patients with new complete conventional dentures were satisfied, 1/3 was neutral, 1/3 was dissatisfied
- The provision of implant-retained overdentures predictably led to less complaints regarding the mandibular denture It also led to a better masticatory performance, but with regard to the relationship between masticatory performance and chewing experience an improvement in masticatory performance did not predictably lead to the same improvement in chewing experience and vice versa
- The clinical results at the 1-year evaluation did not reveal significant differences between the three implant systems However, long-term results remain to be evaluated

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CHAPTER 9

SUMMARY

This thesis is one part of a prospective two-center study about the benefits of implant-retained mandibular overdentures carried out at the University of Nijmegen The other part was completed at the University of Groningen (E M Boerrigter)

This thesis can be divided in two parts The first part describes the results of the two-center study (Chapters 1-4), the second part gives the results of the study performed in Nijmegen only (Chapters 5-7)

The aim of the study was to compare the treatment effects of implant-retained mandibular overdentures with the results of a control treatment The implant systems used were the Brånemark (BRÅ), the IMZ system (IMZ) and the Transmandibular implant system (TMI) Two Brånemark or IMZ implants were connected with a bar, the superstructure of the Transmandibular implant consisted of a triple-bar construction with cantilever extensions Treatment with new conventional complete dentures of high quality (CD) served as the control treatment

In **Chapter 1** - the general introduction - the design of the two-center study is described Only patients with severely resorbed mandibles were selected (symphyseal bone height of 8-15 mm as measured on a standardized lateral cephalogram) and no preprosthetic surgery or implant treatment in the past Treatment was assigned using a balancing procedure, aiming at an equal distribution of patients over the treatment groups with regard to variables that could interfere with the outcome of the study (balancing criteria)

Chapter 2 deals with the material and methods of the study and gives the results of a comparison of the subjective chewing ability of patients with implant-retained mandibular overdentures and patients with new conventional complete dentures One hundred and fifty one patients participated in the study The group with implant-retained overdentures consisted of 91 patients, the complete denture group of 60 patients Since some patients refused the allocated treatment the 'Intention To Treat' principle was applied

Patient's experiences were evaluated before treatment and one year after insertion of the new dentures Results before treatment showed that all patients were dissatisfied with their old mandibular denture and could hardly chew tough or hard foods One year after insertion of the new dentures the group treated with implant-retained mandibular overdentures scored significantly better with respect to subjective chewing ability than the control group, which got a new

denture only The results imply a considerable improvement of the group treated with implants

In **Chapter 3** a comparison is made of the implant overdenture group and the control group with respect to complaints about their denture and with respect to general satisfaction Factor analysis of the complaint questionnaire produced six scales (table 3 3) The general satisfaction rate and three of the six scales of the complaint questionnaire showed significantly better scores for the group treated with implant retained mandibular overdentures than for the control group This was especially related to the scales 'functional complaints lower denture', 'functional complaints in general' and 'neutral space' With respect to denture satisfaction all persons of the group treated with implants were satisfied with their mandibular denture, whereas one third of the control group was satisfied and one third was dissatisfied Implant-retained overdentures appear to provide a more satisfactory solution to the denture-related problems of patients with severely resorbed mandibles than new conventional complete dentures of high quality

Chapter 4.1 deals with the construction of a Clinical Implant Performance scale (CIP-scale) This five point scale was constructed in order to compare the clinical performance of three different implant systems retaining mandibular overdentures All possible problems and complications were considered that probably could occur after implant placement, viz surgical, prosthetic, peri-implant tissue and radiographic The Delphi-method was used to give every problem or complication a score on the CIP-scale After three Delphi-rounds there was almost complete consensus of opinion for more than 91% of the items of the permucosal implant systems and 85% of the items of the transmandibular implant system Although some differences remained it can be concluded that, using the Delphi-method, a reliable scale for the evaluation of clinical performance of implant systems retaining mandibular overdentures is obtained

In **Chapter 4.2** the results of the clinical evaluation 1 year after insertion of the new dentures is described for the two-center part of the study During the healing period one IMZ and one BRÅ-implant were lost One TMI had to be removed because of mobility of three of the four posts immediately after starting the functional loading After 1 year the results of measuring the condition of the peri-implant tissues, radiographic parameters and the CIP-scale showed no significant differences between the three implant-systems

In **Chapter 5** a comparison is made between a group of implant-mucosa supported overdentures on 2 IMZ implants and a group of mainly implant-supported overdentures on a TMI with respect to the part of the study performed in Nijmegen No significant differences were found with regard to experiences with surgical procedures, denture satisfaction and chewing ability These results were unexpected, as the overdentures retained by the transmandibular implant were to a much larger extent supported by the implant than the overdentures retained by 2 permucosal implants

Chapter 6 deals with the comminution of artificial test food during mastication In comparison with the patients wearing implant-retained mandibular overdentures, the patients of the control group with conventional complete dentures needed between 1 5 and 3 6 times more chewing strokes to achieve an equivalent reduction in particle size No differences in masticatory performance and efficiency were found between the IMZ- and the TMI-group The results suggest that the increased retention and stability of the mandibular denture rather than the degree of loading received by the implants or by alveolar mucosa determine the ability to comminute food during mastication

In **Chapter 7** the relationship between the comminution of artificial test food, i e masticatory performance, and the subjective chewing experience is analyzed In a Linear Structural Relation analysis (LISREL) no direct relation ship was found between masticatory performance and functional complaints about the mandibular denture The results show that an improvement in masticatory performance does not always imply a comparable degree of improvement in subjective chewing experience and vice versa

Finally, in **Chapter 8** a general discussion of this study is presented It is concluded that patients treated with implant-retained overdentures compared with a control group of new conventional complete dentures showed less complaints, were more satisfied and had a better subjective chewing ability and masticatory performance One third of the total number of patients treated with new complete dentures was satisfied, 1/3 was neutral and 1/3 was dissatisfied

Clinical results were promising and did not reveal significant differences between the three implant systems 1 year after treatment To assess the possible clinical differences between the three implant systems medium- and long-term evaluation is necessary

SAMENVATTING

Het onderzoek van dit proefschrift is onderdeel van een prospectieve 'two-center' studie naar de meerwaarde van een overkappingsprothese op implantaten in de onderkaak ten opzichte van een conventionele methode en werd uitgevoerd aan de Katholieke Universiteit Nijmegen en de Rijksuniversiteit Groningen

Dit proefschrift doet verslag van het gemeenschappelijke aandeel (Hfdst 1-4) en van het Nijmeegse aandeel (Hfdst 5-7) Het Groningse aandeel wordt beschreven in het proefschrift van Mw E M Boerrigter

Het doel van de studie was de effecten van de behandeling met een overkappingsprothese op implantaten - gebruik makend van drie verschillende implantaatsytemen - te vergelijken met een tot nu toe gebruikelijke conventionele behandelingsmethode Er zijn drie verschillende implantaatsystemen gebruikt het Brånemark-systeem (BRÅ), het IMZ-systeem (IMZ) en het Transmandibulair Implantaatsysteem (TMI) Twee Brånemark of twee IMZ implantaten werden met elkaar verbonden door een bar De suprastructuur van het Transmandibulair implantaat bestond uit een drievoudige-bar constructie met distale extensies De conventionele behandelingsmethode bestond uit het vervaardigen van een nieuwe volledige gebitsprothese van hoge kwaliteit (CD)

In **Hoofdstuk 1** - de algemene introductie - wordt de opzet van de *two-center* studie beschreven Alleen patienten met een sterk geresorbeerde onderkaak werden geselecteerd (kaakhoogte 8-15 mm gemeten op een laterale schedelfoto t h v de symphysis) De patient mocht geen preprothetische chirurgie of implantaatbehandeling hebben ondergaan in het verleden De verschillende behandelingsmethoden werden door balancering aan de hand van een aantal criteria aan de patienten toegewezen

In **Hoofdstuk 2** worden materiaal en methoden beschreven en wordt een vergelijking gemaakt tussen het subjectieve kauwvermogen van de patient met een overkappingsprothese op implantaten en een nieuwe conventionele volledige gebitsprothese In totaal namen 151 patienten deel aan deze studie 91 hiervan werden behandeld met een overkappingsprothese op implantaten, 60 met een nieuwe conventionele gebitsprothese van hoge kwaliteit

Het subjectieve kauwvermogen werd geevalueerd voorafgaand aan de behandeling en één jaar na het plaatsen van de nieuwe gebitsprothese Hieruit bleek dat vóór behandeling alle patienten ontevreden waren over hun oude onderprothese en dat ze veel moeite hadden met het kauwen van taaie en harde voedselsoorten Eén jaar na behandeling konden de patienten behandeld met een

overkappingsprothese op implantaten naar hun eigen mening significant beter taai en hard voedsel kauwen dan de groep behandeld met een conventionele gebitsprothese Zoals bleek uit de vragenlijsten geeft een overkappingsprothese op implantaten naar het oordeel van alle patienten een aanzienlijke verbetering in het kauwvermogen

In **Hoofdstuk 3** worden de klachten over de gebitsprothese, het rapportcijfer en de algemene tevredenheid van de patient met een overkappingsprothese op implantaten vergeleken met die van de patient met een volledige gebitsprothese (controle groep) Factoranalyse van de klachten vragenlijst leverde zes schalen op (tabel 3 3) Na één jaar scoorde de implantaat-groep significant beter dan de groep met de volledige prothese op de schalen 'klachten ondergebit', 'functionele klachten algemeen' en 'neutrale ruimte' Alle patienten met een overkappingsprothese op implantaten waren tevreden over hun onderprothese, van de groep met een volledige gebitsprothese was 1/3 tevreden en 1/3 ontevreden

In **Hoofdstuk 4.1** wordt verslag gedaan van de constructie van een 'Clinical Implant Performance (CIP) scale Deze vijfpunts schaal werd geconstrueerd om de drie implantaat systemen objectief te kunnen vergelijken Hierbij werden alle mogelijke complicaties in aanmerking genomen die konden optreden na het plaatsen van implantaten, t w chirurgische, prothetische, 'peri-implant' en rontgenologische complicaties De Delphi-methode werd gebruikt om elke complicatie een score te geven op de CIP-schaal Na drie Delphi-rondes was er vrijwel complete consensus voor meer dan 85% van de items van de verschillende implantaatsystemen Met behulp van de Delphi-methode is een betrouwbare schaal verkregen om de 'clinical performance' van implantaatsystemen met een overkappingsprothese te evalueren

In **Hoofdstuk 4.2** wordt de klinische evaluatie van de drie verschillende implantaatsystemen (BRÅ, IMZ, TMI) beschreven één jaar na het plaatsen van de overkappingsprothese Tijdens de inhelings-fase gingen 1 IMZ- en 1 BRÅ-implantaat verloren Na functionele belasting ging 1 Transmandibulair implantaat verloren De resultaten van de klinische parameters, de rontgen-scores en de CIP-schaal laten geen significante verschillen zien tussen de drie implantaatsytemen

In **Hoofdstuk 5** worden, voor het 'Nijmeegse' deel van de studie, de ervaringen van de groep met een implantaat-mucosaal gedragen overkappingsprothese op 2 IMZ implantaten vergeleken met de ervaringen van de groep met

een voornamelijk implantaat-gedragen overkappingsprothese op het Transmandibulair implantaat Er waren geen significante verschillen tussen de groepen met betrekking tot de ervaringen met de chirurgische procedure (plaatsen TMI onder algehele anaesthesie, plaatsen IMZ onder lokale anaesthesie), tevredenheid en subjectief kauwvermogen Deze resultaten waren onverwacht aangezien de overkappingsprothese op het TMI meer door het implantaat werd ondersteund dan de overkappingsprothese op 2 IMZ implantaten

In **Hoofdstuk 6** wordt verslag gedaan van de objectieve kauwfunctietest In vergelijking met de patienten met een implantaat overkappingsprothese hadden de patienten met een nieuwe volledige gebitsprothese 1,5 tot 3,6 keer zoveel kauwslagen nodig om dezelfde mate van voedselverkleining te verkrijgen Geen significant verschil werd gevonden tussen de twee implantaatgroepen (TMI - IMZ) De resultaten suggereren dat de toegenomen retentie en stabiliteit van een onderprothese op implantaten de kauwfunctie meer beinvloeden dan de mate van ondersteuning door implantaten

De relatie tussen het objectieve kauwvermogen en de kauwervaringen van de patient wordt geanalyseerd in **Hoofdstuk 7** In een 'Linear Structural Relation analysis' (LISREL) werd geen directe relatie gevonden tussen het objectieve kauwvermogen en de kauwervaringen Uit de resultaten kan worden afgeleid dat een verbetering in kauwvermogen niet eenzelfde mate van verbetering in de kauwervaringen hoeft te geven en andersom

In **Hoofdstuk 8** wordt een algemene beschouwing gegeven over dit onderzoek Geconcludeerd kan worden dat de groep patienten met een implantaat overkappingsprothese vergeleken met de groep met een volledige gebitsprothese minder klachten had, meer tevreden was en een beter objectief en subjectief kauwvermogen had Eén derde van de patienten behandeld met een conventionele gebitsprothese was tevreden, 1/3 neutraal en 1/3 ontevreden

Klinische resultaten wijzen erop dat de drie implantaatsystemen een betrouwbare basis bieden voor een overkappingsprothese, althans gedurende het eerste jaar na plaatsen Lange termijn evaluatie is dan ook zinvol

NAWOORD

Allen die, op welke manier dan ook, een bijdrage hebben geleverd aan het tot stand komen van dit proefschrift wil ik hartelijk danken Daarvan wil ik enkelen speciaal noemen

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- Medewerkers van de afdeling Mond- en Kaakchirurgie, Academisch Ziekenhuis Nijmegen en van de afdeling Mondziekten, Kaakchirurgie en Bijzondere Tandheelkunde van het Academisch Ziekenhuis Groningen voor de prettige samenwerking
- Alle patienten, zonder wie dit onderzoek niet mogelijk zou zijn geweest
- Martin voor het vermogen om in mijn soms negatieve belevingen, altijd weer het positieve zichtbaar te maken en natuurlijk ook voor de computer ondersteuning thuis

CURRICULUM VITAE

Maria Elisabeth Geertman werd geboren op 21 november 1961 te Nijmegen In 1980 behaalde zij het VWO-diploma aan het Canisius college - Mater Dei te Nijmegen Na een jaar biologie te hebben gestudeerd begon zij in 1981 met de studie tandheelkunde In 1986 werd het tandartsdiploma behaald Tot oktober 1989 werkte zij als tandarts in Middelburg Vanaf 1 oktober 1989 is zij part-time werkzaam bij de vakgroep Orale Functieleer, afdeling Volledige Prothese en Maxillo-faciale Prothetiek en het Centrum voor Bijzondere Tandheelkunde van de Faculteit der Medische Wetenschappen van de Katholieke Universiteit Nijmegen Daarnaast is zij werkzaam in de algemene praktijk

Stellingen

bij het proefschrift

Implant-retained mandibular overdentures
clinical evaluation, satisfaction and mastication

Marielle Geertman

12 oktober 1995

1 Een overkappingsprothese op implantaten functioneert zo veel beter dan een conventionele prothese dat nagenoeg alle klachten verdwijnen (dit proefschrift).

2. Het vervaardigen van een volledige prothese heeft bij patiënten met een sterk geresorbeerde onderkaak slechts in ⅓ van het aantal gevallen het gewenste succes (dit proefschrift).

3. De tevredenheid van patiënten met een voornamelijk implantaat-gedragen en met een implantaat-mucosaal gedragen overkappingsprothese verschilt nauwelijks van elkaar (dit proefschrift)

4. Een overkappingsprothese op implantaten brengt het kauwvermogen van de edentate patient met een sterk geresorbeerde onderkaak tenminste weer op het niveau van dat van een prothesedrager zonder problemen (dit proefschrift).

5. De "Clinical Implant Performance scale" zegt meer over het werkelijke succes van implantaten dan de vaak gehanteerde mislukkingspercentages (dit proefschrift).

6. Röntgenologische evaluatie van de conditie van het bot rond implantaten staat nog in de kinderschoenen.

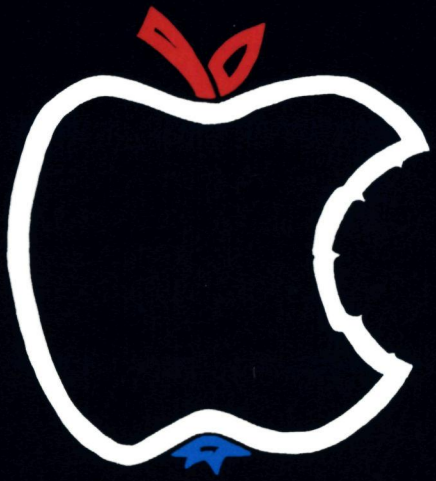
7. Een multi-center studie slaagt alleen als alle lagen van de betrokken organisaties bereid zijn hun eigen belang in te wisselen voor het gezamenlijk belang, hun achterdocht te beteugelen en compromissen te sluiten.

8. Het plaatsen van een overkappingsprothese op implantaten mag niet gezien worden als het einde van de behandeling maar is het begin van continue (na)zorg.

9 Door de gewijzigde verzekeringsaanspraken en tarieven is vooral de prothesepatient die na behandeling nog problemen heeft het kind van de rekening.

10 Niets is zo praktisch als een goede theorie.

11. Als je niet weet waar je naar toe wilt, maakt het ook niet uit welke weg je kiest.



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